A CONSUMER'S PERSPECTIVE ON MEDICAL DEVICES

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

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HOUSE OF REPRESENTATIVES

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A CONSUMER'S PERSPECTIVE ON MEDICAL DEVICES

THURSDAY, MARCH 30, 1995

House of Representatives,
Committee on Commerce,
Subcommittee on Oversight and Investigations,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:02 a.m., in room 2123, Rayburn House Office Building, Hon. Joe Barton (chairman) presiding.

Members present: Representatives Barton, Cox, Burr, Frisa, Wyden, Waxman, Furse, Eshoo, Klink, and Dingell.

Mr. Barton. The subcommittee will come to order.

We want to welcome this first panel before the Oversight and Investigations Subcommittee. This morning our subcommittee will begin its inquiry into the regulatory impact of the Federal Food and Drug Administration on the safety, health, and economic well-being of Americans and the adequacy of the underlying statute, the Food, Drug and Cosmetic Act, which we call the FDCA.

We are going to start with a look at the consumer perspective on the regulation of medical devices. Today we focus on conditions in the medical device market and how the regulatory process impacts patients, physicians, and the businesses that provide the technological advances on which all health and health care consumers depend.

Subsequent hearings will examine the device approval process and the other regulatory functions of the FDA.

There have been assertions by certain groups that the FDA is the target of some kind of witch hunt. I want to assure everyone that this investigation and these hearings will be conducted in a fair, fact-finding manner. This subcommittee has a long and proud history of reaching policy conclusions based on a careful examination of the facts. That tradition will be followed in this inquiry as well as in others undertaken by the subcommittee under my chairmanship.

I know that the full committee chairman, Chairman Bliley of Virginia, shares this position.

This does not mean that we will pull our punches when we find wrongdoing or wrong-headed policy. The chips will fall where they may.

There is little question that the approval of new medical technologies in the United States is too slow, too expensive, and unfortunately sometimes too arbitrary. We intend to find out why and if possible to correct that problem.

I have talked to Commissioner Kessler about this problem and he assures me that the FDA stands ready to cooperate with this investigation. I intend to hold him to his word.

Today's witnesses will provide first-hand testimony regarding the effects that the problems in the medical device approval process have had on their lives, the lives and the health of their patients and their employees. It is not a positive picture.

The constraints that our manufacturers and doctors must labor under in dealing with the FDA sometimes seem to defy common sense. There is no question that the American people demand safe and effective drugs and medical devices. We all depend upon advances in medical technology to extend our lives and to improve our lives' quality. Somewhere along the way the FDA, which is in charge of ensuring that such advances produce safe and efficacious products has apparently lost its direction.

We intend to see that the FDA returns to its core mission. We further intend to see that it uses the resources provided by the taxpayers to regulate both efficiently and fairly.

We further propose to eliminate the sad situation in which medical devices conceived and developed in the United States appear in world markets outside of our Nation well before they are approved for use in our own country. This is unfair to our citizens and unfair to our medical technology firms. Life-saving technology invented here should be available to Americans at the earliest possible date. The cost savings that result from these innovations should accrue to our health care system at the earliest possible date.

Our witnesses have compelling stories to tell and I look forward to hearing from them. We would like to recognize the ranking minority member, Mr. Wyden, for an opening statement, if he so chooses.

Mr. WYDEN. Thank you very much, Mr. Chairman. Today the subcommittee begins a critical series of hearings to assess the role of the Food and Drug Administration in the innovation, development and commercialization of new drugs and medical devices. These hearings provide an opportunity to lay the groundwork for new 21st century policies at the FDA that are good for consumers and good for entrepreneurs.

Virtually no other arm of the government plays a role so pivotal to the health and safety of average Americans.

Fortunately, our taxpayers benefit from having an agency that provides a gold standard of safety and efficacy for health care products. I firmly believe the FDA's public health mission is compatible with entrepreneur-friendly policies that more quickly bring new products to the consumer and create additional jobs. These are not mutually exclusive ideals. It doesn't have to be jobs or safe products. Members of this committee can work on a bipartisan basis for policies that do both.

In that pursuit, let this subcommittee reject cheap rhetoric, ideological myth-making and half-baked anecdotes that have been peddled aggressively by powerful special interest groups since the November election.

Make no mistake about it: The agenda of these extremists, who masquerade as reformers, is to tear down the FDA and give self-interested parties the keys to the medical kingdom.

Some argue that a power-mad FDA captained by a thug is fixated on destroying medical technology firms and that they are succeeding. This argument is hard to swallow given that last year domestic medical device manufacturers enjoyed a $4.7 billion positive balance of trade.

No bureaucracy is without blemish. The FDA is far, far from perfect. Rather, is it a work in progress and function, mission and management have to be carefully and thoroughly scrutinized by the Congress. This subcommittee is going to find problems at the FDA. We will find instances where officials have fumbled, misapplied the law or simply neglected their mission. This is an agency that supervises the introduction of thousands of new and highly technical products and glitches and even systemic failures are inevitable.

The fundamental question is how well the agency functions across a broad spectrum of activity. I expect we will find that they have handled many matters in an acceptable fashion but that they can do better. Good reform requires building a fact-based record. It is appropriate that we begin this effort in a re-assessment of the FDA with respect to medical devices. The Agency's task in this area is largely defined by statutes enacted nearly 20 years ago. Since then there has been a revolution in medical device technology driven by high-speed computer chips, lasers, biotechnology, and dozens of other now ubiquitous innovations.

The question must be where does the system break down and why. There aren't any surprises here. This is not Forrest Gump's box of chocolates. Those who have studied the system extensively know where the system breaks down. The 510(k) process for evaluation of low risk products that may duplicate devices already in the market has often failed to meet the 90-day deadline for action on applications.

Although the FDA in recent months has diminished both backlogs and the average pendency period, more must be done to improve performance.

Class III devices, which are complicated, often implanted, and can pose serious risks if they fail, sometimes get bogged down in the evaluation process for reasons including the Agency's comparative lack of expertise in certain high-tech innovation.

We are all frustrated when low-risk devices take too long to be approved. We would also agree that the stakes are greater with respect to the more complex devices, devices with greater therapeutic benefit also may be potentially more dangerous and therefore their safety and efficacy are subject to greater scrutiny. It's not good enough with these kinds of devices, which could be a heart valve or a pacemaker, to simply trust a company's claims about the product. There is an important and non-transferable government role in checking out these claims.

In recent days the Clinton Administration and the Food and Drug Administration have moved ahead on several significant fronts. Almost 140 devices have been downgraded from Class II status to Class I, and all Class I devices have been exempted from the 510(k) application process. Special requirements for manufacturing insulin and antibiotics have been removed. Manufacturers have been exempted from environmental assessments. The reference list, a blacklist of manufacturers, has been junked. This is a solid beginning but we are far from the finish.

It's my understanding that before the end of this year the Administration will have additional reform announcements which will open up export market opportunities and further reduce the evaluation system's strain on manufacturers.

I intend to offer shortly my own proposals for FDA reform. I look forward to working with my colleagues on both sides of the aisle in pursuing these issues.

Mr. Chairman, I thank you for the time.

Mr. BARTON. I thank the gentleman from Oregon. We'd now recognize the gentleman from North Carolina for any opening statement he may wish to make—Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman. I appreciate the opportunity to participate in what I hope will be the first of many looks at the Food and Drug Administration.

Mr. Chairman, these hearings are about the ongoing ruination of the medical device industry in the United States. This $40 billion industry produces a host of products vital to the lives of millions of Americans while creating the kind of high tech jobs that we need to remain prosperous and competitive well into the next century.

Mr. Chairman, in 1993 the medical device industry had a trade surplus of $4.7 billion. However, the inability of the FDA to review device applications in a timely fashion as is required by law is driving our device industry overseas. If this unfolding tragedy is not stopped quickly, Americans will be forced to endure second class medical care along with job and revenue losses to overseas competitors.

A 1994 study of the Health Care Technology Institute found that unemployment in the medical technological sector, which had grown at an annual average of 3.4 percent between 1988 and 1992, had levelled off in 1993 and began to decline in the first quarter of 1994.

This study also found a decline in venture capital investment in the medical technology industry amounting to $143 million in 1993. I believe that the decline in investment and employment must be laid squarely at the feet of the FDA.

In November 1994 Medtronics, a medical device manufacturer from Minneapolis, announced that it would move its corporate venture offices to the Netherlands to take advantage of a more favorable climate for medical innovation. American Biomed of Woodland, Texas, built a manufacturing plant to produce medical devices for clinical trials in Europe and according to the June 3, 1993 New York Times, the president of the company cited FDA delays as the primary reason. The Times reported that American Biomed is one of the scores of American device companies that have introduced new products abroad as opposed to the U.S. and it is no wonder why more and more U.S. firms are doing this.

The CEO of Interventional Technologies, Inc. of San Diego told the Times that its first device received FDA approval after 26 months of review. The company got permission to begin clinical trials on its second device in Germany in 34 days, but it took 13 months in the U.S.

Mr. Chairman, the medical device approval problem will be solved one way or the other. Either the FDA will promptly comply with the statutory review and approval guidelines which require that devices be approved within 90 or 180 days, depending on whether they are similar to older devices, or new, or the device industry will move off-shore and there will be fewer and fewer applications for the FDA bureaucrats to bother with. Our medical future demands that the FDA review process be fixed.

I yield back my time.

Mr. BARTON. I thank the gentleman from North Carolina.

We would like to recognize the distinguished ranking member of the full committee, Mr. Dingell, for any opening statement that he might wish to make.

Mr. DINGELL. Mr. Chairman, I thank you. Mr. Chairman, I commend you for this hearing today and I commend you for continuing the succession of hearings through which this subcommittee had begun a long and continuing process of scrutinizing the behavior of the FDA, with regard to drugs, foods, and devices.

This is an important continuation of those undertakings, and it follows on the 1993 report—which was adopted by this committee in a bipartisan fashion—entitled "Less Than the Sum of Its Parts." That report was a product of a multi-year, bipartisan investigation of how medical device regulation actually worked.

As today's hearing will show, problems discussed in that report continue. I welcome our witnesses, who will represent a range of individuals and organizations involved in the development and the use of medical devices. They can give us a very useful look at the interactions among patients, doctors, industry, and regulators, in the important work of making safe and effective devices speedily available to the public and in seeing to it that the law, with regard to both efficacy and safety, is carried forward.

The key issue before the Congress in connection with these matters has always been how to promote the benefit to consumers of new devices and how to promote the benefits to the society and the economy of having new devices developed here in this country to be available not only to our people but also to others around the world, while taking appropriate measures to limit risks to consumers from these same devices.

This is a difficult problem and it is one on which the subcommittee has worked with a wide variety of interested parties, including many of those in the industry represented before us today. Those efforts were bipartisan and were directed toward overseeing the regulation of medical device and exploring better ways of promoting and protecting the public health.

We will again need to hear a wide range of views if we are to implement successfully the committee's 1993 recommendations that the Congress consider more effective means of device regulation.

The upcoming series of hearings need to answer a number of important questions.

One, is FDA making sufficient progress in administrative reforms outlined in the subcommittee's report and urged by many others as well?

Two, are these reforms, even if fully implemented, sufficient?

Three, does FDA have enough resources to meet its responsibilities? Do we need to provide the Agency with more resources or offload some of its responsibilities, or some combination of the above?

Four, do we need perhaps to consider new mechanisms for making FDA work or new mechanisms to enable FDA to carry out its responsibilities properly?.

As many of my colleagues here on the committee know, the FDA has begun, under the leadership of this particular subcommittee, to move through the mechanism of using user fees to enable the Agency to hire more adequate numbers of personnel and better skilled personnel. These fees are designed to enable the process of regulation to move forward more rapidly in the areas in which such fees have been approved for use by the Agency.

Five, how can the Congress assure that consumers receive the benefits of technological advances in medical devices as quickly and safely as possible and, also, how can industry receive the benefits of marketing technological devices as quickly and safely as possible so as to contribute not only to the health of the American people but quite honestly, to the competitiveness of American industry?

The medical device industry is critical both to public health and to the economy of this country. The American medical device industry is a world leader. Our regulatory system for medical devices must be a world leader as well and must contribute not only to the safety and the health of the American people but also, quite frankly, to the economic advantages that a strong and viable and healthy industry can give to this economy. I thank you, Mr. Chairman.

Mr. BARTON. I thank the distinguished ranking member of the full committee.

We now recognize the gentleman from New York, Mr. Frisa, for an opening statement.

Mr. FRISA. Thank you, Mr. Chairman, and we welcome the opportunity to begin the important process of trying to fix the broken FDA.

I think we all recognize that the purpose of the FDA is supposed to be to serve people and their mission should be to make the results of technological breakthroughs readily available in order to enhance lives.

The sad truth is that the FDA does not serve people well and does not foster expeditious processing of these new medical devices and the effects of this FDA failure have proven devastating.

In the March-April, 1995 issue of the National Center for Policy Analysis, Dr. Richard Cummins of the American Heart Association is quoted as estimating that 1,000 lives were lost while the FDA red tape prohibited the manufacturer from selling a defibrillator even though the device had already been approved. The manufacturer finally had to go to court to seek relief so that product could be put on the market.

I think the problem here is more than just a classic case of a bureaucracy run amok but it is one that has cost lives and I think it is long time, Mr. Chairman, that we begin the process of saving lives, saving dollars and making the FDA an agency that is responsible and responsive to the American people, and we look forward to hearing testimony to accomplish those ends. Thank you.

Mr. BARTON. I thank the gentleman from New York. We now recognize the gentlelady from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman, for holding this series of hearings on medical devices. Although I am new to this committee I am very familiar with the extensive work that the committee has done in the past on a variety of FDA related issues including the Agency's review, approval and regulation of medical devices.

I accepted the co-chairmanship of the House Medical Technology Caucus and I hope that we can elevate the importance of the issues that these hearings are providing in the Congress and address them in a responsible way and I look forward to doing that both as a member of this committee and the co-chair of the caucus.

The medical technology industry is a major factor in our Nation's economic growth and international competitiveness. In my State of California, where health care technology accounts for more than 140,000 jobs—very good paying jobs, the largest of 142 companies increased their annual revenue by $2 billion in 1992. As we know that there are some things that are wrong inside the FDA, and we need to heighten not only our understanding and awareness, something must be going okay as the revenues have increased.

There are several medical device companies in my own district, which includes Silicon Valley. Indeed, the medical technology and biotechnology industries represent the new wave of innovation in Silicon Valley. All of these companies have achieved high production growth averages, high export growth averages, and high employment averages over the last 5 years.

We know that the government hasn't kept up with the rapid technological pace and growth of the industry and a failure to address these problems threatens the industry, which we don't want, and the scores of jobs that the industry supports.

Of course, most importantly, the failure to address these issues threatens the ability of the companies to provide life-saving, cost-saving therapies, treatments and cures for the American people. That is really where the rubber meets the road and that is at the top and should always be at the top of our agenda, so I look forward to hearing our distinguished panel today, the witnesses that have come before us. I appreciate their willingness to testify and I know that I am going to learn more and hopefully we can bring together the most important set of book-ends, how we can make the Agency more effective for the American people while we support the industries in what they are able to do and are doing as we are sitting here listening to our panel.

So thank you, Mr. Chairman, and thank you to the panel of witnesses.

Mr. BARTON. I thank the gentlelady and now recognize the distinguished Vice Chairman of this subcommittee, Mr. Cox of California for an opening statement.

Mr. COX. Thank you, Mr. Chairman. In the last Congress on a different subcommittee where I was the ranking member, I had the opportunity to look through a series of hearings the regulatory credit crunch and I see significant parallels between that problem and the problem that we are addressing today.

The problem is this. Under FIRREA, we found that bureaucrats had no personal risk if they unduly restricted credit. They may have had personal risk if they permitted credit to expand and as a result we had a regulatory credit crunch.

The bureaucrats have no downside for doing nothing in those circumstances. The FDA is going to tell us later on that they are setting new records for review times and approvals, that they have approved an unprecedented number of supplemental applications or changes in manufacturing processes of already approved products, but we are going to hear first from witnesses who tell us that that is not the whole story.

In fact, we have a bureaucratic crunch at the FDA involving lifesaving devices that is even more damaging to America than was the regulatory credit crunch. The cost to America when we were talking about the unavailability of credit was lost jobs, lost capital formation, businesses destroyed, but the cost to America in this case is lives lost, not to mention higher prices for the devices and diminished access to health care for every American as a consequence.

It is becoming increasingly clear in recent years that the FDA's excessive regulation of medical devices is stifling the development of devices that can improve the quality of health care of patients in America and around the world. It is well documented, notwithstanding what I have just read and what the FDA is going to tell us later on, that the FDA is taking longer and longer to review and approve medical device applications.

FDA's record with approvals of incremental changes in an already approved device of 510(k) has deteriorated. The Food, Drug and Cosmetics Act requires the FDA to complete reviews within 90 days, but the average review time is up significantly from 82 days in 1989 to 216 days last year in 1994.

FDA's record with approvals of breakthrough technology, premarket or PMA approval, is equally dismal. The law expressly requires FDA to complete its review within 180 days but actual review time has ballooned from an average of 348 days in 1989 to 823 days last year in 1994.

The purpose of today's hearing is to listen to consumer perspectives on medical device regulation. This is especially important because it is not often enough that we hear of the enormously destructive consequences that these intolerable delays are having on the quality of public health.

I am very much looking forward to the testimony of our two panels of witnesses today. I am confident that their personal stories will provide Members of Congress with a better sense of how excessive delays in medical device regulation are robbing patients and health care professionals of access to products and tools that can save lives.

Recently, this full committee enacted landmark legislation requiring bureaucrats to take into account the costs of their regulations as well as the benefits. Perhaps today's testimony will lead us to enactment of similar changes to the 1976 medical device amendments to the Food, Drug and Cosmetics Act that will make bureaucrats sensitive to the cost to public health of doing nothing as well as the cost of doing something.

I thank the chairman.

Mr. BARTON. I thank the gentleman from California and the Chair will now recognize the third consecutive Californian for an opening statement, the Honorable Henry Waxman of California.

Mr. WAXMAN. I thank the chairman. I am pleased to participate in this hearing.

Over the last several months we have heard a lot about the need for regulatory reform. The House responding to rhetoric and horror stories, some of dubious voracity, has passed two pieces of very ill-advised legislation, one placing a moratorium on regulations and another imposing on regulatory agencies extensive, costly and senseless activities all in the name of so-called improvement in risk assessment and cost/benefit analysis.

Fortunately for our citizens, neither of these bills seems likely to be passed in the Senate in their present form.

The haste with which the House dealt with those important matters and the reliance placed on half-truths and bumper sticker slogans did not cast us in a good light. We need to act on facts, not anecdotes, to be responsible legislators. I am pleased that this subcommittee appears to be taking a more deliberate approach to analyzing the regulation of medical devices.

I don't think any of us can sit here and say the FDA is a perfect agency and that all of its procedures and policies are absolutely right. This would be no more thoughtful than saying everything is wrong. The truth lies somewhere in the middle. The FDA has recognized this, the President has recognized it, there are a number of reforms at FDA of its practices and policies as part of the President's own initiative to improve Federal regulation. Several of those recommendations which the FDA is in the process of implementing deal with the medical device regulations. The President and FDA have told us they will continue an initiative that FDA began last year to exempt certain low-risk products from having to submit applications to FDA. The first set of these exemptions was published in the Federal Register last year when FDA exempted 148 categories of so-called Class I devices and that exemption meant that manufacturers will be able to market well over 1,000 individual products per year without submitting applications to FDA.

Within the next several months, FDA will down-classify and then exempt from the application process another 140 types of devices in Class II, again thousands of individual products. But we do want the FDA to protect us from products that are going to cause harm to the public, products that are unsafe, that are deceptive, incorrectly labeled and advertised or just plan don't work. I think we ought to keep in mind that there is a balance and to simply talk about bureaucrats with disdain is not a very encouraging way for the FDA to be taking on this responsibility to achieve this balance.

I do want to correct the record. The American Heart Association disavows the statement that Congressman Frisa quoted someone else as attributing to them in terms of the number of lost lives attributed to devices not approved. And contrary to another statement we have heard just this morning, the medical device industry is not facing imminent demise in the United States. As a matter of fact, one of the problems at the FDA is the fact that there has been such a dramatic increase in the number of applications for new devices that the FDA with shrinking resources has not been able to deal with all the new applications from all the new device manufacturers.

Mr. Chairman, we need to look at reforms. Some can be done by the FDA itself, others may require Congress to act. What we need is input from a variety of experts including industry representatives and others. Congress needs to approach its development of proposals for regulatory reform and for FDA reform in the same responsible way.

I think we must be careful, aware and knowledgeable as we approach these reforms to do it in a responsible manner. I would hope that people on both sides of the aisle and all members of this committee will keep an open mind to all witnesses to hear what they have to say and not just accept one point of view and then leave the hearing, not to hear what the witnesses have to say.

Thank you, Mr. Chairman.

Mr. BARTON. I thank the gentleman from California.

I would recognize the gentlelady from Oregon, Ms. Furse, for an opening statement if she wishes.

Ms. FURSE. Thank you, Mr. Chairman. I don't have an opening statement but I do want to say how deeply involved I am in this very issue and I am looking forward to Mr. Sklar's testimony. I, too, have a very beloved daughter who has diabetes and it certainly is a very, very important issue that he is going to bring to us.

Thank you for holding the hearing.

Mr. BARTON. I thank the lady.

We now are ready to hear from our first panel. Before we do that, there are some bookkeeping things that we need to take care of. Each of you should be aware that this subcommittee is an investigative subcommittee and, as such, it has had the practice of taking testimony under oath.

Do any of you have any objection to testifying under oath?

[No response.]

Mr. BARTON. We would also like to advise you that, under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you so desire to be advised by counsel during your testimony?

[No response.]

Mr. BARTON. If you would each stand up and raise your right hand.

[Witnesses sworn.]

Mr. BARTON. Be seated.

We are going to start with Mr. Glenn Sklar. He is an attorney employed by the Office of the General Counsel at the Department of Health and Human Services. His wife, Linda, is a physician who is seated directly behind him and they have a young, 2-year-old daughter, Bonnie, who is also seated directly behind him, in her mother's lap. Bonnie suffers from juvenile diabetes and must be tested for sugar in her blood every 4 hours. This test currently involves drawing a sample of blood using a lancet, which is very painful. The alternative is a noninvasive procedure using a glucose sensor which is an infrared device that measures blood sugar without a needle. It has not been approved by the FDA despite an application that has been pending since January 1994.

Mr. Sklar, we would like to hear your testimony.

STATEMENTS OF GLENN SKLAR, ESQ.; EDWARD Q. YAVITZ, M.D.; NEIL KAHANOVITZ, M.D.; CHARLES E. JOHNSTON, II, M.D. AND JOEL J. NOBEL, M.D.

Mr. SKLAR. Good morning. I am Glenn Sklar and I am here to testify on behalf of a very special little girl, my 2-year-old daughter, Bonnie. Bonnie is right behind me.

I am not affiliated or acting on behalf of any company, trade group or political group. Improving the quality of life for my daughter, who has diabetes, is strictly a nonpartisan, nonproprietary issue.

When Bonnie was just 14 months old, she was diagnosed with juvenile diabetes. My wife, Linda, and I were totally devastated. Linda, being a physician, knew exactly what this meant for Bonnie: A lifetime of insulin injections and six to eight finger punctures each day to test her blood sugar. If we didn't do a good job controlling her blood sugar, Bonnie could fall victim to the debilitating medical complications of diabetes 20 years down the road. End stage renal disease, requiring dialysis, premature heart disease or even blindness.

Aware of the consequences, we began a daily blood testing regimen of blood sugar testing. It is the same daily blood testing regimen which the Nation's 80,000 children with juvenile diabetes are subjected to each day. It goes something like this:

Each morning, I place Bonnie on my lap, she squirms away, I catch her, reassure her that I love her and then I am forced to puncture her finger with the lancet and place a drop of her blood on a meter which yields a blood sugar reading. This blood testing regimen is repeated at 10 a.m., 2 p.m., 6 p.m., 10 p.m. and at 2 in the morning while Bonnie sleeps and any other time when her behavior indicates that her blood sugar is not quite right.

Actually, it is my wife, Linda, who bears the brunt of this blood testing. She chose to put her career as a physician on hold in order to monitor Bonnie's blood sugar around the clock.

Mr. Chairman, ending this daily blood testing regimen is not some far-fetched fantasy of mine. Indeed, there is a device known as the noninvasive glucose sensor, which you just mentioned, which could test Bonnie's blood sugar painlessly and accurately. It actually calibrates blood sugar through the skin without piercing the skin using infrared technology.

I would like to take a minute to tell this committee what this device would mean to my family and other families like ours. What this device would mean to Bonnie is that she would no longer be subjected to six to eight finger punctures each day which leave her fingers sore and bruised. What this device would mean to my wife, Linda, is that she could resume her career as a medical doctor. We could simply have someone at home running noninvasive tests as often as we wished and phoning those results in to us at work.

What this device would mean to the Nation's 80,000 children with juvenile diabetes is that they, too, could test in a pain-free manner. Indeed, their parents would no longer be subjected to the psychological torment of inflicting pain on their own child every day of the year.

Finally, what this device would mean to the American taxpayer is reduced Federal benefit payments. I know this for a fact. As a public interest attorney working for the Federal Government in the disability litigation area, I have seen first hand the close link between noncompliant diabetics who don't test themselves because it hurts and the terrible medical complications of diabetes. These complications are debilitating for the diabetic; they are also very expensive for the American taxpayer.

Indeed, one out of every seven health care dollars in America goes toward diabetes or diabetes-related complication. It is just a staggering amount of money.

I can't tell you how frustrating it is to know that this device exists but Bonnie and thousands of other children and adults can't benefit from it. Why is the FDA dragging its feet on this important device? Why has a 90-day product review, a legal review, taken upwards of 390 days and counting?

Each morning when I put Bonnie on my lap and she says, Daddy, don't do that, don't hurt my finger, just once, just once, I would like to be able to tell her, no, Bonnie, we don't have to do that today. Better yet, I pray for the day when I could say, no, Bonnie, we don't ever have to do this again. It is that important, Mr. Chairman, and I am glad people are here today talking about it.

The time for FDA action on the noninvasive glucose sensor is now. The children are waiting.

Thank you.

[The prepared statement of Glenn Sklar follows:]

Prepared Statement of Glenn Sklar, Esquire

Good morning. I'm Glenn Sklar, and I'm here to testify on behalf of a very special little girl—my two-year old daughter, Bonnie. I am not affiliated or acting on behalf of any company, trade group, or political group. Improving the quality of life for my daughter who has diabetes is strictly a non-partisan, nonproprietary issue.

When Bonnie was just 14 months old, she was diagnosed with juvenile diabetes. My wife Linda and I were totally devastated. Linda, being a physician, knew what this meant for Bonnie—a lifetime of insulin injections and 6-8 finger punctures each day to test her blood sugar levels. And if we didn't do a good job controlling her blood sugar, Bonnie could fall victim to the debilitating medical complications of diabetes 20 years down the road—end stage renal disease requiring dialysis, premature heart disease, or even blindness. Aware of the consequences, we began a daily regimen of blood sugar testing. It's the same blood testing regimen which the nation's 80,000 children with juvenile diabetes are subjected to each day. It goes something like this...

Each morning, I place Bonnie on my lap, she squirms away. I catch her, reassure her that I love her, and then I'm forced to puncture her finger with a lancer and place a drop of her blood on a meter which yields a blood sugar reading. This blood testing regimen is repeated at 10 a.m., 2 p.m., 6 p.m., 10 p.m., at 2 o'clock in the morning while Bonnie sleeps, and any other time when her behavior indicates that her blood sugar is abnormal. Actually, it's my wife Linda who bears the brunt of this blood testing. She chose to put her career as a physician on hold in order to monitor Bonnie's blood sugar around the clock.

Ending this daily regimen is not some far-fetched fantasy of mine. Indeed, there is a device, the noninvasive glucose sensor, which could test Bonnie's blood sugar painlessly and accurately. It calibrates blood sugar through the skin using infrared technology without actually puncturing the skin. I'd like to take a minute to describe what this device and others like it would mean to my family and other families like ours.

What this device would mean to Bonnie is that she would no longer be subjected to 6-8 finger punctures each day that leave her fingers sore and bruised.

What this device would mean to my wife is that she could resume her career as a medical doctor. We could simply have someone testing Bonnie at home as frequently as we wished, and that person could phone the results in to us at work.

What this device would mean to the nation's 80,000 children with juvenile diabetes—and the 14 million adults with adult onset diabetes—is that they would no longer be subjected to this painful blood testing regimen. Indeed, parents would no longer be subjected to the psychological torment of inflicting pain on their own children.

And finally, what this device would mean to the American taxpayer is reduced Federal benefit payments. I know this for a fact. As a public interest attorney practicing in the disability litigation area, I have seen first hand the correlation between noncompliant diabetics who don't test their blood sugar due to the pain, and the devastating medical complications of diabetes. These medical complications are debilitating for the diabetic; and they are expensive for the taxpayer. At the present time, one of every seven health care dollars in America goes to treating diabetes-related illnesses.

I want to stress that my wife and I have no complaints about the device we now use to test Bonnie's blood sugar levels, and we are thankful for it. The ability to accurately monitor blood sugar levels has opened the door to a better quality of life for millions of diabetics. But advancement is the nature of technology, and the noninvasive glucose sensors represent the next generation of devices for monitoring blood sugar. And these new devices may help the nation's research scientists make a major leap forward in the development of the artificial pancreas—a promising area in the search for a cure. But the noninvasive glucose sensor is beyond our reach. It is awaiting approval by the Food and Drug Administration. I can't tell you how frustrating it is to know that this device exists but Bonnie and thousands of other children can't benefit from it.

Mr. Chairman, this device means so much to so many people... *especially* my little girl. Why is the FDA dragging its feet in rendering a formal decision on this important device? Why has a product review that the law says should take 90 days taken more than 390 days? Each morning when I put Bonnie on my lap and she tells me "Daddy, don't hurt my finger," I pray for the day when I can say "It's okay Bonnie, we don't have to hurt your finger today... or ever again." It's that important, Mr. Chairman.

The time for action on the noninvasive glucose sensor is now. The children are waiting.

Mr. BARTON. I want to thank you, Mr. Sklar. And let the record indicate that my father is a diabetic and although he is not 2 years old, obviously, he performs this same procedure and it is very painful.

We would now like to hear from Dr. Charles E. Johnston. Dr. Johnston is an orthopedic surgeon, Medical Director of Research and Assistant Chief of Staff at the Texas Scottish Rite Hospital in Dallas, Texas. This is a nonprofit organization that provides free orthopedic care to children.

Dr. Johnston is not only a skilled surgeon, he is also an innovator in the use of medical devices and orthopedic treatment. He has invented a spinal fixation device that has FDA approval for certain uses but that also has unapproved uses. The firm that has the license to manufacture this device cannot train surgeons in the off-label uses. As a result, doctors have had to fly to Germany to get this training.

We welcome Dr. Johnston.

STATEMENT OF CHARLES E. JOHNSTON, II, M.D.

Dr. JOHNSTON. Thank you, Mr. Chairman and members of the subcommittee.

Today I would like to tell you about two things, how physicians and engineers are involved in the development of innovative new medical devices and the difficulties that are encountered in an interfering and inflexible regulatory environment when we try to advance the quality of health care in the United States.

In the mid-1980's, I was involved in the development of a new spinal implant system called the TSRH Instrumentation, named after the hospital where we developed it. The purpose of this spinal instrumentation system was to improve the surgical management of spinal disease and deformity through better internal fixation.

This technique eliminates postoperative casts and braces, it promotes faster bone healing, it provides better correction of deformities so that basically patients are getting a more rapid and fuller recovery. This type of innovation is a direct outgrowth of the marriage between biomechanical research and clinical experience, particularly the experience of over 10 years of surgical practice and the knowledge of deficiencies in existing other systems. The main improvement in our system was that it was more user friendly, easier to implant and it was more versatile since it could be used anywhere in the spine from the neck to the pelvis.

A small device manufacturing firm took over the marketing of the device and an active medical education program teaching surgeons the correct indications and technique, which is the common way that medical progress is made in a doctor-to-doctor educational process.

The device became the most commonly used fixation system in the United States, which is probably testimony to its widespread acceptance by the surgical community of our technical and educational improvements.

Surgeons are trained to innovate and they do this basically every day in determining the best treatment for their individual patients. This is, in fact, what surgical practice is, to devise a new method of treatment when the existing methods are impossible or inadequate.

For the TSRH system, plates, screws, hooks and other devices were basically modifications and improvements of existing implants so their approval by the FDA was made easier because of the 510(k) approval technique. However, for reasons known only to itself, the FDA has attempted to regulate the use of one of the implants in the system, a bone screw, by limiting its use to only anterior vertebral fixation and sacral fixation. It has attempted to forbid the use in other lumbar pedicle areas. These are nonapproved, although they are anatomically almost identical to the approved areas.

The irritating thing about this is that pedicle use is very common surgical practice, especially in Europe and it is accepted by the surgical community, the orthopedic community, as the best site of attachment in many cases.

Engineers will understand that internal fixation is only as good as the bone/metal interface, in other words where the metal is attached to the bone. If our pedicle fixation is the strongest site, proven by both laboratory bench testing and by surgical experience, the FDA is dictating to us where—what location is not acceptable and what technique is not acceptable and this flies in the face of our laboratory and surgical experience.

There is no justification or precedent for this and it threatens to limit the ability of a surgeon to design the best treatment for his individual patient based upon what the surgical findings dictate. In other words, if a screw may be best or, in fact, if it may be the only anatomical site where we can achieve fixation in the spine. It suggests that the FDA reviewer somehow can make operative decisions before surgery and they can do this better than the surgeon even when, as I mentioned before, these FDA mandates contradict biomechanical and clinical practice.

The other consequences, which are nonmedical, are in fact the FDA is mandating what I have to tell my patients when I mention to them that I might have to use an off-label or nonapproved method. This is direct interference in the doctor/patient relationship and you can imagine what unnecessary anxiety it might cause to the patient.

Finally, the non-FDA approved use of bone screws in the spine has been used as evidence in civil litigation so that the implication is that an off-label use by a surgeon, he has somehow committed malpractice. Faced with this possibility of litigation, it is no wonder that some surgeons are intimidated to the point of withholding this treatment even though, again, it may be the best and is widely accepted for fear of litigation. This recent FDA foray into regulating surgery is counterproductive to the innovative practice of surgery and to providing the best patient care.

The second thing I would like to tell you about is an experience with the overly restrictive FDA regulation of what I would call a breakthrough surgical device, a rib prosthesis. Its use is indicated in children who have severe congenital spinal curvature or scoliosis combined with rib fusions. As a result, the chest volume is extremely restricted so that there is no room for the internal organs and consequently is life threatening and, until now, there has been no effective treatment until a colleague in mine in San Antonio developed an expandable prosthesis.

FDA approval was initially permitted, and correctly so, only by the inventor and the surgery could only be performed in San Antonio. However, because of the "experimental nature" of this prosthesis, children had to be separated from their home environment and referred to San Antonio for surgery.

The most serious problem has been that, after 4 years of careful, conscientious documentation of the safety and efficacy of this device, its moving to a lower classification device has been delayed and there does not appear to be any explanation why the approval process is so slow. I would like to therefore ask Congress and the committee to consider that the FDA's methods are stifling our innovation, stifling the medical advances which can be made by such innovative procedures and to please stop interfering with established and accepted surgical practice unjustifiably and interfering in the doctor/patient relationship. The FDA's role should be facilitative and not obstructive.

Thank you.

[The prepared statement of Charles E. Johnston, II, follows:]

PREPARED STATEMENT OF CHARLES E. JOHNSTON, II, M.D.

INTRODUCTION

Mr. Chairman and members of the Subcommittee, thank you for inviting me to speak with you about the role of medical devices and the FDA in my medical prac-

tice as an orthopedic surgeon at Texas Scottish Rite Hospital for Children (TSRHC) in Dallas, Texas, where I am the Medical Director of Research and Assistant Chief of Staff. I have attached a copy of my curriculum vitae and I ask that it and my written statement be incorporated in the record. The Texas Scottish Rite Hospital for Children is a non-profit institution that provides orthopedic care without charge to children in Texas and in some cases from around the world.

I want to tell the Committee about two things: 1) how physicians get involved in the development of innovative new medical devices; and 2) the difficulties that an inflexible regulatory environment creates for advancing the quality of health care in the United States. I will use two examples from my own experience to illustrate these points.

DEVELOPMENT OF TSRH™ SPINAL IMPLANT SYSTEM

In some ways, orthopedic surgeons are like engineers and mechanics in that we use a wide variety of hardware and tools in order to design, build, or repair complex structures: in this case, the musculo-skeletal system of the human body instead of buildings, roads, or machines. I have with me a "tool kit" that I helped develop for use in surgery on the spine. As you can see, it contains metal plates, screws, and other metal devices. Most of these components, or things similar to them, have been used by surgeons for various indications for a long time—I learned about many of them while still in medical school. We use them to rigidly stabilize broken or diseased bones so that they can heal properly.

The spine is essential to life as we know it. Without it, we could not even move our heads or raise our arms and legs. When the spine is injured by trauma or disease it can be life-threatening, and it almost always compromises day-to-day movement that we normally take for granted, like walking, reaching, or sitting. At TSRHC, we treat a lot of children with spine problems, from the mild to the most severe. Providing effective treatment for these young people can literally change the course of their lives. It often makes the difference between a life confined to a wheelchair, possibly dependant on a caretaker, and a life of total independence and freedom.

Back in the 1970's & early 80's, surgery to correct fractures of the vertebrae, severe scoliosis, also known as curvature of the spine, and other serious conditions of the spine were treated with a variety of techniques and devices. After surgery, individuals with severe back problems were often put in whole or partial body casts for six months or more following surgery. Sometimes it was necessary to secure a rigid metal frame on the outside of the body, using external screws in the skull and hips to keep the patient from moving or bending while the injury healed.

The advent of internal fixation devices, such as the device I have here, was an extraordinary improvement for many patients, patients who now are able to lead progressively more active, normal lives very soon after the surgery. Internal spinal fixation devices not only make the treatment of back problems easier for patients, they yield better final results and actually cost less in time and money than earlier treatments. Many people in the orthopaedic service industry say that such a revolutionary device would not be approved by the FDA today.

Nonetheless, in the mid-80's I found that the existing internal fixation hardware we had at that time still had significant limitations and problems in achieving adequate fixation for deformities or fractures. It occurred to me that if we took existing implants already in use, such as bone screws, hooks and plates, that with further modification and mechanical improvements they would provide better stability while a spinal fusion or other procedure healed, and it would provide greater relief than would be possible using existing fixation devices.

Research hospitals, like TSRHC, have always relied on the ingenuity of their staff to solve the medical problems that arise when existing treatments fail. Most medical advances depend on this informal development process, which often is triggered by a particular patient's needs. For example, sometimes when you have a patient on the operating table you discover that an anatomical variant exists, such as when a large artery is located in a different position than usual, making it impossible to use a device the way you planned. You find you could use it if it were one half inch shorter or bent differently. You assess the situation and decide to cut off one half inch, and bend the implant. Sometimes you must use a device in a different or new way to provide the best treatment for a particular patient's spinal problem. The treatment works and the patient is fine.

Surgeons in particular are trained to do this—to devise new treatment strategies and procedures when existing ones fail—in the operating room if necessary. Whether it involves using a clamp designed for one purpose or for something else, substituting one type of suture for another, or trying a drug designed to treat bone cancer to treat breast cancer, the strategy, device, or procedure used is chosen solely by the physician, based on his or her informed medical judgment, in consultation with colleagues and the patient.

So I took the idea about a better spinal fixation device to other surgeons and the engineers at TSRHC. Starting as little more than rough drawings the idea was refined and the engineers crafted the types of metal implants we needed. Before too long, we had the spinal fixation system we needed, known as TSRH instrumentation. It was tried in patients for whom the existing devices had failed and for whom there was no other treatment. It worked well and provided substantial relief to my patients.

Also typical of most advances in medicine, other surgeons with whom I worked or was acquainted learned about the new fixation system through informal discussions. They too wanted access to the device and wanted to learn when and how it could be used. Since TSRHC is a hospital and not a device manufacturer, we licensed our idea to a start-up medical device manufacturer, who then sought and obtained FDA review, and started producing the TSRH™ spinal implant system for commercial use. In this case we were very lucky. The little start-up company has had good success with the device. Other physicians learned about the procedure for using this new implant system through continuing education programs and articles published in medical practice journals. The device has been very effective and is one of the most commonly used spinal implants available.

This example illustrates the importance of the physician's ability to freely use training, experience and medical judgment to devise new treatments, devices, and procedures as necessary. It demonstrates how patient care can be improved by the ingenuity of the medical professional. It shows why we call it the "practice" of medicine. Medical care constantly evolves and advances every time a patient presents with condition that is sufficiently different to require a new approach.

Despite the success most patients and surgeons have had with spinal fixation devices, and despite the medical necessity for every physician to use tools and devices in a manner that will be most beneficial to an individual patient, the FDA recently has tried to dictate specifically *how* spinal fixation devices can be used and *when* they can be used. The FDA has said that certain spinal fixation devices, such as pedicle screws, can only be used for treating one very specific disease of the spine, spondylolisthesis; can only be attached to two vertebrae in the lumbar area; and that the disease must have progressed to a specific level of severity. The FDA also has attempted to dictate what I must tell my patients about the FDAs position when I discuss treatment options with them.

The FDAs position is without medical justification or precedent. First, the FDA has no authority or expertise to regulate the decisions I make regarding patient care, nor does it have the authority to dictate how I interact with my patients. From what I understand, most of the FDAs device reviewers have not attended medical school, much less spent five years in an orthopaedic residency, or ten years in surgical practice. Further, it is medically untenable to state that these devices are appropriate for a certain type of spondylolisthesis, one possible use, but not for spinal fractures, scoliosis, or other appropriate conditions that involve the very same parts of the anatomy. To make matters worse, the FDAs position is being used as evidence in civil litigation that a physician who uses these spinal fixation devices in a manner that the FDA has not expressly reviewed has somehow committed malpractice.

Faced with the possibility of a malpractice lawsuit for being innovative and patient-oriented, many physicians are intimidated into following FDAs dictates, instead of doing what physicians have always done—select treatment based on what is best for their patient. As a physician, I find that troubling, just as I find the FDAs current policies and practices very wrong. If the FDA is allowed to regulate surgical practice, its policies could seriously undermine innovation and the advances in medical care that come from this type of innovation.

Experimental Device For Severe Scoliosis

Another experience of note involved efforts at TSRHC to obtain potentially lifesaving treatment for very young children with extremely severe congenital rib deformities and spinal curvature—so severe that they essentially have insufficient chest volume for their internal organs. Until recently, we were unable to provide much hope to these children or their parents because we had no effective treatment for their condition.

However, I learned about an innovative device developed by a colleague in San Antonio. The device would correct the deformity and act as artificial ribs for the children. The device and treatment were planned so that as the children grew, the device could be expanded to keep pace. Although the device was still "experimental," it seemed to be the hope of growth of the thorax and lungs, for which we have no other treatment.

We treat children without charge at TSRHC, and because of our expertise, rarely do we need to refer patients to other doctors or hospitals. In this case, however, the FDA regulations prevented us from providing an innovative treatment, since the FDA required the children to obtain treatment in San Antonio.

The FDA approval of this device initially was limited to permit only the physician who developed the device to use it, and farther, required the surgery to be performed only in San Antonio. This was appropriate, although it meant that the children had to be separated from their home environment, had to undergo the hardship of traveling, and had to suffer through other difficulties that would not have occurred if we could have done the surgery locally at TSRHC. The final insult came when the children's health insurance carrier, provided through the parents' employers, would not authorize payment for the care in San Antonio because the treatment was considered "experimental."

I went to San Antonio to learn about the new medical device and to participate in the surgery with the inventor. Without FDA restrictions, we at TSRHC could have then obtained the device itself from the same source as the inventor. Then, we could have performed the surgery at no cost and without the unnecessary trauma caused by the travel to San Antonio. In fact, that is precisely how medical advances were spread from one physician to another, from one hospital to another, throughout the history of medicine. We could have used that process here but for the restrictive scope of the FDA permit.

Ultimately, we were able to convince the health insurance companies to pay for the surgery and the children received the treatment and it has been successful. As for the device, it is still regarded as "experimental," subject to the same FDA restrictions that have been in place for four years. During that time, the safety and efficacy of this device have been conscientiously documented to the FDA by the inventor in his initial series of patients. The inventor, who is somewhat frustrated with FDAs oversight of the device, informed me that the FDA may approve clinical trials with the device in other locations by other surgeons. But there is no prediction about if or when such a device might be commercially available.

In this instance, the delay in getting from experiment to marketable product is easier to understand than delays associated with products that are already on the market in some form in other countries or which are not breakthrough, life-sustaining devices. But as a surgeon who has had, and may have patients to whom this device could make a huge difference in outcome because we have no existing effective treatment, I wonder why FDA did not permit more surgeons and hospitals to use the device earlier in order to gather more data on its safety and effectiveness. Surely that would have been desirable considering the lack of an alternative treatment. By what authority can the FDA override the medical tradition by which learning and innovation have been transmitted from doctor to doctor? These are questions the FDA should be asked by the Congress because they ultimately will determine the scope and rate at which medical care will advance in the United States.

CONCLUSION

In conclusion, physicians in clinical practice have had little reason to be knowledgeable about the FDA because, in theory, the FDA does not regulate how physicians practice medicine. In real life and in recent times, however, FDA regulation increasingly has begun to impinge on the choices I may make as a physician and research director to provide the best available medical care to my patients.

The two points that I hope to have conveyed to the Subcommittee are that if FDA is permitted to continue interfering with medical judgments in this manner, it will: 1) stifle innovation in the practice of medicine; and 2) diminish the quality of medical care available to the American people both ultimately leading to higher medical costs. Both of these results are unacceptable. I hope the Subcommittee, and Congress as a whole, will act to confine the FDA to its proper role and thereby promote steady innovation in medicine and an environment where the best possible health care is, in fact, the care that the American people are getting.

Mr. BARTON. Doctor, you have some sort of an exhibit there. Do you want to explain what that is before we go to our next——

Dr. JOHNSTON. Do I have time, Mr. Chairman?

Mr. BARTON. We will give you 30 seconds. You brought that all the way from Texas, you ought to at least get to hold it up and let us——

Dr. JOHNSTON. What I brought was a model of the spine with some of these implants placed on it to demonstrate to the committee how some of the screw anatomical sites such as these on the front of the spine and these in the sacrum are the approved sites where the FDA has approved their use.

Mr. BARTON. So you can use a screw in those locations?

Dr. JOHNSTON. These are approved.

Mr. BARTON. Okay.

Dr. JOHNSTON. But in these other anatomical locations which are extremely near and extremely similar, they are not approved.

Mr. BARTON. So what do you do in those locations if you can't use the screw?

Dr. JOHNSTON. Well, we have very poor methods of fixation in many types of surgical conditions and so our ability to internally fix the spine is extremely limited. This is a situation where a surgeon must devise the best treatment. This is the best treatment and so we have to advise our patients, for example, ahead of time that we may need to use an off-label use during their procedure.

Mr. BARTON. Thank you.

We would now like to hear from Dr. Joel Nobel. Dr. Nobel is a physician and the head of the Emergency Care Research Institute. He is a past vice chairman of the Consumers Union and currently sits on the Board of Directors of that organization as chairman of its Technical Policy Committee.

Among his many accomplishments, Dr. Nobel directs the Emergency Care Research Institute, World Health Organization Subcommittee, which is collaborating with the Center for Information Transfer on Medical Devices. He is an expert on the technology, regulatory structure and international markets available for such medical devices.

Dr. Nobel has some comments about why the United States may be losing its competitive edge in developing this medical breakthrough technology.

Dr. Nobel.

STATEMENT OF JOEL J. NOBEL, M.D.

Mr. NOBEL. Thank you, Mr. Chairman.

First, I stress that I am not speaking on behalf of either the World Health Organization or Consumers Union, but for my own organization which is a nonprofit research agency that evaluates medical equipment very much the way Consumer Reports evaluates cars and toasters.

For 24 years, we have also operated an international problem reporting network for defects in medical devices. We accept no grants, gifts, contracts from medical device or pharmaceutical firms, no employee may consult for or own stock in such firms, and every employee's Federal Income Tax Return is examined annually to ensure that our organizational responsibility rests on a solid foundation of individual integrity.

In other words, we are detached from the process of profitmaking, and what I will try to convey are several of the core issues that are amplified in my formal statement for the record.

The terms of the public debate about medical devices have already been framed as industry profits and international competition versus patient safety, regulation versus free market virtues, and consumer protection versus FDA bashing. While this makes good political theater, it fails the issues. Trivializing legitimate criticism as FDA bashing is simply unacceptable. Voices have been raised precisely because ears have been closed. Likewise, calling for deconstruction of the FDA and indiscriminately privatizing critical functions is contrary to the public interest. We can successfully offload some of the FDA's burden to the private sector if we do it in a thoughtful manner with clear lines of responsibility.

Medical devices, some 5,000 of them, are highly diverse in nature, design, clinical functions, manufacturing processes, users and use environment. Legislative and regulatory generalizations alone do not deal effectively with this diversity. Fortunately, there are also many nonregulatory mechanisms that help protect patients from flawed devices, but regulatory reform, product liability reform, and the concept of Federal preemption should be considered together rather than as unrelated issues, otherwise we will seriously weaken patient protection.

Patients are more often harmed by user error in judgment and application of devices than by intrinsic manufacturing or design flaws. Neither legislation or regulatory priorities have focused on this more significant aspect of the problem and, despite repeated denials, pharmaceutical regulatory concepts have undermined effective management of device safety and effectiveness from the outset.

Congress has asked the FDA to do things which cannot be done or should not be done. We have failed collectively to distinguish between what is ideologically desirable and technically possible and practical to implement. There is a chronic failure to distinguish between the very significant and the very trivial and to put our energies and priorities and focus in the right place.

It is no more possible to estimate the number of patients who have been harmed because of the absence of an as yet unapproved device than to quantify the number of patients who have been harmed by defective devices.

Device law and regulation is reduced to practice on a daily basis by speeches, directives, commands, arguments, body language, threats, fear and a host of other very human communications tools. Were they examined in detail as they are practiced, it would raise serious questions and angry answers about due process.

If you ask the wrong questions, you will get the wrong answers. Industry claims that device approvals take too long, make industry noncompetitive, increase the cost of care and deprive patients of critical technologies have some truth, but there are also some counterpoints.

They tend to lead to a call for more FDA resources or privatization to speed the approval processes. Both answers are probably wrong. We believe it is the approval process, the underlying philosophy and values that is deficient, and if you speed up a deficient process, you will get less efficiency and more errors. So what is wrong with the process comes back to the rigidity of laws, regulation and the impulse of government to substitute rules for thinking, and common sense in individual and new circumstances. There is a serious mismatch between a traditional bureaucratically modelled rule-laden agency and its coping with rapidly developed technologies in a volatile information environment.

If we wish to regulate medical devices efficiently and optimize patient welfare, minimize costs, and satisfy the temporal needs of industry, none of which are incompatible at the heart of it, we have to develop a new regulatory paradigm and paradoxically, what the FDA may need is more discretionary authority, and a new organizational value system so that it can exercise common sense approaches rather than its cookbook methods.

The combination of regulatory rigidity, power and arrogance is at the core of many objections. No rational person in the health community or industry rejects regulation per se, they just want it to work effectively and fairly and preferably quickly. Many companies believe it is advantageous to be part of a regulated industry, but paradoxically, the combination of regulation, approvals and Federal preemption is already proving contrary to the interest of patients.

The vast majority of individuals I have encountered at the FDA over 30 years are intelligent, thoughtful and sensitive. They know as much or more about agency limitations as we outsiders do, and should be full participants in this process of constructive change. Patients need less political and economic ideology and more intellectual creativity in developing rational methods to do this job effectively, and we at ECRI hope to contribute to this process fairly and effectively.

Thank you for the privilege of testifying. I would also like to correct, if I may, one set of assertions that was made before the witnesses played their role, with due respect to Mr. Waxman, the detailed case history of the Laedral defibrillator and Dr. Cummins and the American Heart Association is extremely complex and was not done justice. We believe that in this particular case, the FDA was technically wrong, clinically wrong, morally and legally wrong, and if the details were revealed in full, honest bloom, you would be absolutely appalled at the FDA competence and behavior.

Thank you.

[The prepared statement of Joel J. Nobel follows:]

PREPARED STATEMENT OF JOEL J. NOBEL, M.D.

INTRODUCTION

The organization I direct, ECRI, is a nonprofit health services research agency whose mission is to improve patient care. Our 30-year focus has been on healthcare technology. Our 210-person interdisciplinary staff operates a *Consumer Reports*-like medical product evaluation program and a broader healthcare technology assessment program that encompasses devices, drugs, biotechnologies, and medical and surgical procedures. For 24 years, we have operated an international medical device problem reporting system and investigated patient injuries and deaths caused by medical devices and their users. To ensure objectivity, we have tough conflict-of-interest controls. We accept no grants, gifts, or contracts from medical device or pharmaceutical firms; no employee may consult for or own stock in such firms; and every employee's federal income tax return is examined each year to ensure that our organizational responsibility rests on a solid foundation of individual integrity.

OVERVIEW

Medical devices are legally defined as devices, apparatus, or systems used for the prevention, diagnosis, or treatment of disease in humans that do not normally enter metabolic pathways. While the qualification appears to distinguish devices from drugs, the real world does not conform to regulatory semantics. Technology frequently evolves new forms that link what was previously distinct, and regulators extend boundaries beyond original intent.

There are approximately 5,000 distinct generic types of devices and more than one million brands, models, and sizes produced worldwide. They range from simple disposable devices, such as tongue depressors and gauze pads, to complex systems, such as computed tomography scanners or magnetic resonance imagers. Between these extremes are devices such as blood chemistry analyzers, ECG monitors, or surgical lasers. Approximately 700 are temporarily or permanently implanted products, about 1,300 are capital equipment with a unit value exceeding U.S.$500, and approximately 2,000 are specialized types of surgical instruments.

In the United States, this disparate collection of entities is produced by approximately 5,000 manufacturers. The vast majority of U.S. medical device manufacturing firms are quite small and very specialized and have fewer than 50 employees. There are a relatively few large national or multinational manufacturers with either highly specialized or very diverse and extensive product lines. Several huge firms produce and distribute comprehensive arrays of devices. Some firms specialize in catalog sales of medical equipment directly to consumers. Others, very small ones, fabricate and fit custom-made devices to patients upon a physician's prescription. In addition to direct sales by manufacturers and their field sales forces, there are tens of thousands of importers, distributors, dealers, and pharmacies that sell medical devices.

CLASSIFICATION

Medical devices fall into several commonsense classes that are helpful in thinking about this highly diverse collection of entities. For example:

—Implanted devices versus nonimplanted devices and active implants versus nonactive implants (e.g., a pacemaker versus a bone plate)
—Single-use (disposable) devices versus nondisposable devices (e.g., a syringe versus a leg brace)
—Diagnostic devices versus therapeutic devices (e.g., an ECG versus a defibrillator)
—Energy-emitting devices versus non-energy-emitting devices (e.g., an x-ray machine or electrosurgical unit versus a suction pump)
—Life-support devices versus non-life-support devices (e.g., a ventilator versus an ECG monitor)

Such groupings help to understand broad similarities and distinctions between entities and the general risks associated with them. Implanted, or invasive, devices, for example, may, in turn, be temporary (a urinary catheter) or permanent (a hip joint). But all implants tend to share two common risks: infection and tissue reaction.

Energy-emitting devices may emit ionizing radiation (a diagnostic x-ray machine, CT scanner, or cobalt therapy unit) or nonionizing radiation or energy. Nonionizing forms are, in turn, divided into:

—Electrical energy (defibrillator, electroconvulsive therapy unit, neuromuscular stimulator)
—High-frequency electricity (electrosurgical unit)
—Microwave radiation (diathermy machine)
—Thermal radiation (infant incubator, heating pad)
—Ultrasonic radiation (fetal monitor, blood flow detector, imaging system)
—Light (phototherapy unit, laser)

Differentiating between energy- and non-energy-emitting devices and the types of energy emitted is useful because there are specific risks and needed safeguards associated with each type of energy. Most energy-emitting devices can harm living cells. With some, the intended clinical effect is through such destruction (e.g., radiotherapy, laser surgery). Sometimes harm occurs; a heating pad burns a patient. The mechanism is thermal radiation, but the cause of the event may not be a product defect. It may be poor blood circulation to dissipate heat, reduced pain threshold caused by neurologic damage, or failure to heed instructions and to limit the exposure time or temperature.

These types of technical groupings overlap current regulatory groupings. Legislatively mandated FDA regulations classify devices as follows:

- Class I is for low-risk, simple devices, such as dental floss or simple surgical instruments, that are subject to *general controls* that apply to all devices regardless of class.
- Class II is for devices that cannot be classified in Class I because there is insufficient information to show that the general controls alone can ensure their safety and effectiveness (e.g., imaging equipment, dialysis systems). They are subject to *special controls* to ensure safety and effectiveness.
- Class III designates devices where there is too little information to determine if Class I or II controls provide reasonable assurance; examples are life-support devices or devices critical to prevent impairment of health or devices that present a potential unreasonable risk of illness or injury. Heart valves, breast implants, and artificial knee joints are Class III types.

While there are obviously many ways to group or classify devices, in the ultimate analysis, medical device design problems or hazards generally involve a very specific brand and model of device with highly specific performance and safety characteristics and, sometimes, very specific and narrow clinical applications. Congress and the FDA first tried to apply broad general rules to specific devices and events. Next, very detailed and complex rituals were developed to cope with narrower and narrower issues, and increasingly specific rules were and are applied inappropriately. *The mismatch between regulatory requirements and realities has grown, and there is now, too often, an inability to distinguish between the trivial and the significant and to treat them differently.* This has a significant cost in time, money, and human energy. Adverse effects for patients, not just industry, inevitably attend blind application of the rules. The rules then become more dangerous than the devices. While specific examples are legion, let us focus, instead, on general concepts.

KEY CONCEPTS AND TERMS

There are certain general concepts and terms that are frequently involved in any consideration of medical devices.

- *Approval:* For a medical device to be marketed in the United States, it must first be shown to be safe and effective to the satisfaction of the Food and Drug Administration's Center for Devices and Radiological Health (FDA-CDRH). This is accomplished by one of two processes, both of which can be long and costly. FDA-CDRH "approval," through either premarket notification or approval, means that the manufacturer is legally allowed to market the device in the United States and define its usage in its marketing literature. It also binds the manufacturer to certain postmarket requirements, such as restriction of sale, continuing evaluation and reporting, or specific labeling.
- *Cost-effectiveness:* Cost-effectiveness measures health benefits for a given cost. The cost-effectiveness of most devices and their cost-effectiveness compared with that of devices fulfilling the same functions usually cannot be proven in advance of market diffusion. This is why, with all due respect, proposed concepts of having the FDA "regulate" cost-effectiveness as part of the device approval process, together with safety and efficacy, cannot work. Demonstrating cost-effectiveness is far more difficult than demonstrating safety and efficacy.
- *Effectiveness:* Effectiveness is the measure of efficacy under real-world conditions, following wide diffusion beyond research centers with their idealized conditions and highly knowledgeable and motivated innovators who are sometimes afflicted by hubris and excessive pride of authorship or have, too often, hidden financial interests.
- *Efficacy:* Efficacy is the ability of a diagnostic or therapeutic modality to fulfill its intended clinical purpose under optimum conditions. It is best measured by carefully designed and implemented clinical trials and is best judged by formal technology assessment studies once the data from valid clinical trials are available.
- *Off-label Use:* In theory, FDA-CDRH "approval" does not limit clinicians' use or application of the device, for these are the province of hospital review boards and the scientific community. For example, while lasers are "approved" for genitourinary surgery, FDA-CDRH will not allow manufacturers to state in their product literature that lasers can be used to treat benign prostatic hyperplasia (BPH) or perform transurethral resection of the prostate (TURP) because using a laser for these narrow purposes has not been shown to FDA-CDRH to be "safe and effective," as compared with a pre-1976 or legally marketed device. Nor will FDA permit manufacturers to distribute peer-reviewed articles from the scientific literature that examine such "off-label" use, raising legitimate questions about free flow of information.

- *Premarket Approval (PMA):* A PMA shows FDA-CDRH, through clinical data, that the device has been thoroughly tested to identify its safety and efficacy in specific instances.
- *Premarket Notification:* This notification informs FDA-CDRH, through documentation, that the device is substantially equivalent (it will have similar safety and efficacy) to a device that either was marketed before 1976 or is legally marketed as a Class I or Class II device. This is also known as "510(k) clearance" (named after its section of the law).
- *Safety:* There is no such thing as absolute safety. Safety is a systems concept, rather than simply a product attribute. An intrinsically safe product without adequate user manuals or training to guide clinical applications may prove dangerous. Intrinsic product safety is only a part of the safety systems concept and includes such factors as electrical leakage current protection in patient monitors, protective incompatibility of gas fittings in anesthesia machines, and human factors design that decreases the risk of error by following proper conventions (e.g., power is increased by turning a knob clockwise rather than counterclockwise).

  Safety, as a systems concept, extends not only to the training and competence of the user, but also to the reliability of supporting services, such as electrical and medical gas distribution systems, and to periodic preventive maintenance and safety inspections by clinical engineers. Safety, especially for medical emergency equipment and life-support equipment, is also closely linked to reliability.

  Above all, safety is a risk-benefit balance that may be defined in general terms or with regard to specific patients. For a given patient, the risk-benefit equation may have a different answer than the regulatory answer for patients in the aggregate. It is also why FDA's overreaching to control information flow to health professionals and the behavior of those health professionals has dangers.
- *Technology Assessment:* Technology assessment is the analytical process by which technologies are identified as appropriate for limited or widespread use, taking into account such factors as efficacy, safety, reliability, cost-effectiveness, and competing methods of diagnosis or therapy or disease prevention. Technology assessment also typically considers the broad, ethical, legal, and economic aspects of a technology, as well as disease prevalence and significance addressed by the technology. The FDA is tasked with approving safety and efficacy only. Technology assessment is a broad intellectual process exercised by both public agencies and private-sector organizations.
- *Technology Diffusion:* Technology diffusion is the degree to which a specific technology is adopted and comes into broad use. From the producer's viewpoint, diffusion has two components: the general acceptance and utilization of the technology and the producer's market share. From the perspective of health planners, the value of a technology and its diffusion are judged against all related health and economic priorities. Diffusion that precedes proof that significant health gains will accrue or that competes for resources better spent on other health measures is considered undesirable. However, efforts to limit technology diffusion in the United States through regulation have, generally, proved counterproductive because of inverted incentives inherent to the legislation or regulations. It is difficult to strike an optimum balance between free-market overdiffusion and a restrictive central planning process. The real solution, now beginning to operate, is limitation of reimbursement for health services.

USE ENVIRONMENT

The environment in which medical devices are used and the people who use them are highly varied. Use environments range from hospitals, freestanding clinics, and doctors' offices to ambulances, accident sites, ships, and aircraft and field hospitals. They include homes, schools, and the workplace, as well as remote or mobile village clinics. The use environment may affect the proper function of devices not designed specifically to operate in that environment (e.g., exhaled patient breaths may condense and freeze resuscitator valves in cold climates). Low-frequency vibration in helicopters may separate ventilation and tracheostomy tube connectors. High-humidity environments may cause electrical or electronic equipment to fail. Low-humidity environments may cause failures through electrostatic discharges. Electromagnetic interference, which can be radiated (through the air) or conducted (through power lines or common conductors), may interfere with the proper function of equipment or cause inappropriate or dangerous interactions between medical devices.

Because of the rapid growth of home healthcare as an alternative to more costly hospital-based care, the use of medical technology is being decentralized. As the healthcare environment shifts from a highly controlled setting, where regulations, standards, and peer pressure (in the form of tissue committees, quality assurance audits, and risk managers) function, to a relatively uncontrolled and undisciplined environment, the potential for harm is changing. Patient records are likely to be less thorough. Inspection and preventive maintenance of equipment and related records may be less detailed, if they exist at all. In addition to a poorly controlled environment and relatively poor documentation, the number and character of the participants is changing. Where patients and family members bear some or much responsibility for the proper application or operational maintenance of medical devices, the related responsibilities of manufacturers, distributors, rental agencies, home healthcare agencies, and their personnel may be perceived differently.

USERS

Medical device users range from family physicians, physician specialists, pharmacists, nurses, doctors' assistants, technologists, technicians, and nurse's aids to patients and their families, police, paramedics, ski patrols, army medics, and navy corpsmen. They include adults, children, and bystanders. Some patients or family members become remarkably knowledgeable and proficient about medical devices, despite a lack of formal medical or engineering training, and take an extremely active role in their own care or that of family members. Others lack the motivation or competence to do so effectively.

While there is a general belief that most medical devices in hospitals are used by physicians, this is generally untrue except in the surgical specialties. In medical and surgical nursing units, radiology, the clinical laboratory, the heart station, and many other hospital areas, most medical devices are applied by nurses, technicians, and technologists. Many such individuals have become quite specialized (e.g., respiratory therapists, perfusionists, cardiopulmonary technicians, hematology technicians). In the clinical laboratory, however, more sophisticated machines are able to decrease the need for human manipulation of specimens and reagents and manual recording of data. Microprocessors and robotic equipment are beginning to replace some functions previously exercised by humans. This adds the complexity of software to the regulatory envelope.

PATIENTS

Patients receive the benefits and, on occasion, experience adverse effects associated with medical devices. There are issues of omission and commission. Technology may be unavailable for reasons that vary from reimbursement limitations or lack of health insurance to regulatory delay in approving devices, or existing technologies may cause injury or death through product design and manufacturing deficiencies, user error, inadequate maintenance, or delayed replacement.

From the patient's perspective, there are six types of medical devices:

—Common entities the patient uses in this normal course of living (e.g., a thermometer, vaporizer, bandage).

—Entities the patient uses because of trauma or disease (e.g., crutches, blood glucose meter, wheelchair, oxygen delivery system).

—Implants to overcome chronic dysfunction, such as a pacemaker or artificial joint. Critical implants such as automatic internal defibrillators often lead to fears or complex psychological issues.

—Life-support equipment, such as a dialysis machine or a ventilator, upon which significant psychological, as well as physiologic, dependency is placed.

—Everything else behind the scenes that supports the patient's care in the clinical laboratory or surgical suite or imaging department.

—Miracle or disaster devices created or sensationalized by the media.

During serious acute illness, patients frequently invest medical devices with special, sometimes magical properties. It is not uncommon, for example, for patients to believe that a physiologic monitor, such as an ECG monitor or pulse oximeter, is actually keeping them alive, although, in fact, it is merely reporting their physiologic status. Patients being weaned from a coronary intensive care unit, for example, often develop anxiety about leaving what to them is clearly a protective envelope of devices. Conversely, media publicity about implants, almost always exaggerated and devoid of perspective, causes significant anxiety among patients, sometimes bordering on panic, and drains substantial energy from the health system.

DRUGS VERSUS DEVICES

Pharmaceuticals and medical devices are sometimes perceived to have common characteristics by legislators or by regulatory agency personnel who have traditionally been responsible for controlling drugs. Drugs and devices are, in fact, very different in fundamental nature, and each requires a very different understanding and experience to deal with it effectively. Despite denials and qualifications, device legislation and regulation in the United States *are* heavily based on the pharmaceutical model. The key distinctions between drugs and devices include development processes, clinical testing, product life cycles, prescribing, and users. The failure to appreciate the distinctions contributes significantly to the burden of both regulators and manufacturers.

An especially significant distinction is the development process, which involves entirely different intellectual disciplines and the product development cycle and life cycle. Drugs are typically developed over an 8- to 15-year period and, if successful, are sold for decades. Most devices are typically developed in 1 to 3 years, become obsolete, and are off the market in 3 to 7 years. *This temporal distinction is critical.* It means that the short development and product life cycle must be linked to relatively rapid clinical trials and speedy scientific review and regulatory processes leading to approval. When approval time consumes almost half the product's life cycle, something is seriously out of balance. Abbreviated development and premarket approval, in turn, makes effective and responsive postmarket product surveillance, problem reporting networks, and user education all the more important to protect patients. Current device regulation and its implementation is temporally mismatched to reality, and postmarket surveillance methods are simultaneously more costly, less effective, and more limited in scope than they should be. Good manufacturing practices (GMP) may expend great energy dealing with relatively unimportant details and may be falsely premised on the assumption that perfectly documented processes have perfect outcomes. The consequences of approval delays may impact patients, as well as manufacturers and investors, negatively.

Clinical trial design criteria derived from the drug model are sometimes blindly and inappropriately applied to devices. They are often unrealistic, impossible to implement, and frequently unnecessary to achieve safety goals or demonstration of efficacy.

Drugs are prescribed by a physician to meet the needs of a specific patient and are provided by a pharmacist, who compounds the drug or obtains the drug from a distributor or pharmaceutical manufacturer. In an institution, a nurse may administer the drug or, at home and at work, the patient may self-administer it.

Devices have a rather different, more complex, and varied chain for prescribing and administration. Some are purchased directly by their patient end users (e.g., a walker, bandage, wheelchair) or on their behalf by a friend or family member. Others are purchased by physicians or other health professionals to use on patients (e.g., a blood pressure set, stethoscope). Some are purchased by dealers who may rent devices to patients (e.g., electric beds, oxygen system). Most diagnostic and therapeutic devices and implants, however, are purchased by healthcare facilities, typically hospitals, freestanding clinical centers, group practices, and nursing homes. While many devices, especially implants, are specified by physicians, a great number of other devices are chosen by materials managers, purchasing agents, or, in the case of complex systems used by many individuals (such as patient monitoring systems), by institutional committees. Unlike drugs, which are typically self-administered or given by a nurse, "administration" of a device frequently involves a surgical or cardiac catheterization team or several technologists or a respiratory therapist.

Many diagnostic and therapeutic devices also require periodic safety and performance inspections, preventive maintenance, and repairs. Drugs do not. Most drugs, once used, then vanish. Those supporting activities are carried out by clinical engineers and biomedical engineering technicians, who may be hospital employees or independent contractors or who may work for manufacturers, distributors, or independent service organizations.

Responsibility for the "prescription," acquisition, clinical application, or proper function of devices is thus far more complex and diffuse than it is for drugs. The prescribing tradition for drugs by physicians, and the associated authority to do so, also tends to handicap physicians' understanding and acceptance of the legitimate and critical roles that others, such as biomedical engineers and materials managers or clinical technologists and nurses, can and should play in decision making about equipment selection and acquisition. And while medical schools teach clinical pharmacology, few provide effective instruction about healthcare technology.

Finally and paradoxically, the pharmaceutical model of regulation for devices has been abandoned in the one critical area where it is probably most important. It is widely accepted that drugs have side effects, and that associated risk-benefit concept has always been accepted. Devices, it seems to be assumed, are never allowed to have any side effects or present risks. Adverse effects are assumed to arise from flawed design or manufacturing processes, user error, or criminal intent. The risk-benefit equation is poorly balanced. The paradox within the paradox is that the concept of postmarket surveillance assumes that deficiencies will arise and corrections can be made, but premarket approval processes insist on degrees of perfection and proof that are often unrealistic and have a poor risk-benefit balance. It is not simply that approvals take too long, but also that the value system that underlies the process and, therefore, these processes themselves are defective.

REGULATION

Regulation of medical devices exists in a number of nations, and no two regulatory systems are the same. Such systems reflect, of course, national traditions of law, culture, and economic resources.

In some nations with regulation of medical devices, that function is exercised by a department of the same government agency that is responsible for drugs. In others, the function is distinct and separate. In some countries (e.g., the United States), the ability to bring a new device to the marketplace is based on proof of efficacy and safety elucidated through manufacturer-supported clinical trials and scientific review of that data by a regulatory agency. In others, greater reliance is placed on formal standards and third-party testing agencies. And in still other nations, especially those that import a high proportion of their medical devices, greater priority is placed on simple registration of devices and manufacturers and, increasingly, postmarket surveillance or problem reporting systems. There is no solid evidence available yet to suggest that one system is superior to others in preventing medical device related adverse effects or that very costly and complex approaches produce superior results to relatively simple and inexpensive approaches. The complexity of the U.S. device regulatory system has made it almost impossible to evaluate either its virtues or its deficiencies clearly, and critics and supporters are usually reduced to focusing on singular examples, horror stories, or very broad trends—such as recent emigration of the U.S. device industry. Quantitative data on device problems or FDA productivity must be examined very thoughtfully. There are assumptions and still more numbers behind the numbers.

In the United States, regulation is relatively detached from other national objectives, such as industrial development and trade. In other nations, they are more often closely linked. The original, primary purpose of the European Union regulatory system was to reduce trade barriers and promote commerce. The U.S. system was premised exclusively on patient safety. ECRI believes, in fact, that protecting patients should, indeed, be accorded the highest value, but we do not believe this is incompatible with economic or competitive success for industry. It is not a matter of competing interests. More thoughtfully implemented regulations would better serve both patients *and* industry, as well as the health community and the nation.

Regulations derive from legislation, and both are implemented within the framework of the U.S. Constitution. Due process attends this continuum of authority. But practical day-to-day FDA operations involve many activities that adjust general rules to narrow and specific circumstances in which exceptions are often the rule—and all too often the exception rather than the inappropriate rule is punished. Due process is absent from many FDA activities. Speeches, issuances of "guidelines" and "interpretations," formal and informal meetings (often with 6 to 10 times as many FDA personnel as fearful supplicants), the controversial "reference list" (considered by many as bureaucratese for blacklisting), heavenward glances or body language, punitive attitudes, overt threats and intimidation, and many other routine mechanisms are used to extend regulation. It is a natural human process when there are few limits on power and neither the inclination nor obligation to perceive or admit error.

The regulated (manufacturers, distributors, importers, exporters, healthcare facilities, etc.) are fearful and afraid to speak up most of the time. The public debate is, therefore, less than candid. Emboldened by access to new political ears, voices may yet be heard. Some believe the FDA has greatly exceeded its legislative mandate. Many believe the FDA has violated First Amendment guarantees of free speech by restricting information flow among scientific journals, manufacturers, and physicians—when the obvious alternative, in the American tradition, is to provide better counterinformation. In science, good information usually drives out bad information. Open debate is superior to suppression of information with which the FDA disagrees if, for no other reason, than the FDA is not always right.

In the ultimate analysis, the basic issue is excessive power in one place—regardless of the competence with which it is wielded at a given moment or by whom. Congress has granted unto the FDA the normally separated and balanced powers of the executive, legislative, and judicial branches of our national government. Abuse of power, obviously anticipated by the framers of the Constitution, is therefore inevitable.

DEVELOPMENT

Development of medical devices has changed significantly over the past 35 years, paralleling changes in society and industry, as well as the growth of scientific and engineering knowledge that began during World War II and accelerated in the 1950s and early 1960s. Traditionally, most medical devices were developed by individual physicians, physiologists, and solo entrepreneurs. The x-ray machine, electrocardiograph, basic laboratory photometer, electrosurgical unit, heart-lung machine, and virtually all surgical instruments emerged from the minds and efforts of such individuals. These devices tended to be mechanical or relatively simple electromechanical or, later, simple electronic devices. More than a few were developed by an engineer and physician working together.

By the late-1950s, however, an expanding electronic industry, growing development of synthetic materials, and burgeoning knowledge of physiology, pathology, engineering, and production processes began to shift the focus of medical device research and development from individuals in medicine to industry. The physician's and physiologist's intuitive part-time tinkering with mechanical and electrical components and materials, which were relatively easy to understand, was practically replaced by a world of more complex electronics design, which required a strong base of theoretical, as well as practical, engineering knowledge.

The growing aerospace effort accelerated this process of growing sophistication in materials, design, electronics, computers, reliability engineering, information displays, and other areas. Increased specialization and the parallel need for design teams, effective industrial organization, and greater capitalization for development, production, and distribution continues to grow today. New regulatory requirements for proof of safety and efficacy have further intensified this shift. The mere specialization of knowledge needed to deal with the U.S. FDA, for example, makes part-time inventing far less feasible and attractive. Regulations' "hassle factor" has strangled the creative energies that underpin invention, and the cost of coping with regulation is well beyond the individual medical device inventor of even a decade or two ago.

Development of a product still starts, inevitably, with one person having the kernel of a new idea. That person is now, however, more likely to be the employee of a medical device company with a market orientation than an individual physician or nurse trying to meet a practical need they have identified.

LEGAL ISSUES

Product liability, or fear of it, and the litigious climate of the United States also have a very significant effect on the development and marketing of medical devices. Fear of liability has certainly buried many products at conceptual, development, production, or marketing phases, even in the absence of any hint that the specific product presented a special problem or safety risk. Current efforts at product liability reform are, in our view, likely to restore a reasonable balance between patient and industry interests. However, there is another legal issue, the concept of federal preemption, which is not simply contrary to the interests of patients, but the health community, as well. *A new pattern of court decisions has assumed that if the FDA approves a product, both product and manufacturer are a protected species and the manufacturer may not be sued.* Product liability reform at the legislative level is a sideshow compared to the impact of these court decisions. In effect, the courts have extended sovereign immunity to private corporations. This is simply unacceptable.

The notion that FDA approval ensures patient protection is bizarre. ECRI investigates hundreds of patient injuries and deaths each year. They are all caused by FDA-cleared devices. We perceive little real connection between FDA clearance and safety. We can see no reason why a manufacturer should be economically protected from the consequences of a design flaw or manufacturing defect. The elimination of this pressure on manufacturers will prove pernicious and will soon make it possible to game the system. Manufacturers are not dumb. A one-time user fee of $52,000 for a device cleared in a premarket approval (PMA) and sovereign immunity are cheaper than product liability insurance premiums or one judgment for a 510(k)-approved device. And some courts have even extended immunity to 510(k) devices.

Trial lawyers, encountering zippers on the manufacturers' pockets, will go elsewhere—to the user and health community by default. *Preemption, in effect, forecloses public awareness and debate about medical device safety.* The FDA already requires time-consuming approval of *improvements* to currently marketed devices, creating a disincentive for product improvements. Preemption strengthens this disincentive. The federal government is sending manufacturers the wrong message.

STANDARDS

Many national and international agencies, both governmental and nongovernmental, are engaged in development and promulgation of design, safety, and performance standards for medical devices. Thousands of such standards exist, and there is a growing effort to ensure international compatibility of standards through organizations such as the International Electrotechnical Commission (EEC) and International Organization for Standardization (ISO) and through regional efforts such as those of the European Community and its organizations, such as CENELEC.

While standards may seem, intuitively, of unqualified benefit, they are not without their limitations, including the following:

- The substantial amount of time and investment taken to create them that has actually delayed safety improvements.
- The impulse to use standards to lock out imports.
- The use of standards to generate testing agency fees for products that have already been tested by other competent testing organizations.
- The relative lack of clinical, as contrasted with engineering, significance of many standards.
- The tendency of standards to memorialize already superseded scientific knowledge.
- The domination of standards-making bodies by industry.
- The fact that standards require agreement. Agreement requires similar experience and data that come, typically, at the stage of third-generation products-by which time most competing devices have very similar characteristics.

Despite these and other disadvantages, Medical device standards will continue to play a significant and growing role in patient safety and international trade.

WHITHER DEVICE REGULATION?

As Congress considers options for regulatory reform for medical devices, it will fail to have a long-range, constructive impact unless it confronts several fundamental issues. The FDA and the nation's patients need and deserve some very thoughtful new legislative instructions. What the health community, Congress, and even much of industry has not yet realized is that the FDA, several years ago, moved from regulating medical devices to centrally managing an entire industry and virtually every aspect of its behavior, except when, from whom, and how it obtains investment capital.

Before the existence of device legislation in this country, the vast majority of medical devices did their job as expected, the vast majority of health professionals using these devices helped patients, and the vast majority of patients were better off for it.

Please consider that there are four dancers on the medical device stage. They include patients, the health professionals who serve them, the manufacturers who provide the tools, and regulators. If you were forced to make a choice about eliminating any one of the dancers, whom would you pick? The intuitively obvious answer would be to eliminate the regulators, since they make the least social contribution. I am in no way suggesting we eliminate regulation; we need it. But I pose the question merely to restore a balanced perspective.

There are a number of regulatory and *nonregulatory* mechanisms that protect patients from harmful devices, and no single regulatory or nonregulatory factor can be credited with a predominating positive impact. While the regulatory tools are premarket approval, special controls, use of standards, postmarket surveillance, and good manufacturing practices, please understand that these are rigid, paper-based proxies for a very fluid reality. That is, incidently, why our organization, ECRI, examines and tests products rather than paper. There are many nonregulatory pressures and activities that also protect patients, and even in the absence of regulatory controls, these other mechanisms would still confer significant protection. At the manufacturer level, they include competition and the desire to excel, professionalism of design engineers, fear of product liability lawsuits, a genuine desire to do good and avoid harm, and an understanding that long-term economic gain comes from superior performance and many other marketplace factors.

At the user level, many of these same forces are at work, reinforced by peer review, formal risk management departments, a wish to make wise choices about technology by hospital staff, widespread availability of information about product experience, comparative testing results, databases on product problems, and scores of other mechanisms, such as hospital liability and physician malpractice fears. Legislative and regulatory development has ignored such nonregulatory factors and failed to exploit them. What we have failed to do, as a nation, is to construct from all of these elements a system that makes it in everyone's self-interest to function in the best possible manner. We urge Congress to examine these mechanisms concurrently in order to achieve an optimum balance and cost-effective regulation.

Most medical device related injuries and deaths are caused by user error in judgment and application. Both regulations and the academic and user community have failed to come to grips with this because it is easier to control 5,000 manufacturers than more than 8 million healthcare workers. By focusing exclusively on both the positive and pernicious aspects of device regulation, we may be looking at the wrong target. We have been spending vast national resources to deal with the smaller part of the problem. The incontrovertible fact is that even if regulators were able to ensure that every device was perfect throughout its development and product life cycle, which is impossible to do, most related adverse effects will not be avoided. In short, if prevention of harm to patients is the objective of our national investment, we lack a balanced portfolio.

Most failures of regulatory agencies to fulfill their missions are explained in terms of inadequate resources to do the job. *Therefore, the best way for a regulatory agency to be accorded more power, money, and personnel is to fail at its mission.* This negative incentive to perform is transparent to any detached observer. The rest of the world doesn't function this way because we know it doesn't work. Organizations in the private sector match the resources to the specific job or do the job anyway, without the resources, by working smarter, harder, and faster. Given our broader national priorities and the relevant insignificance of medical devices in the grand scheme of things, how does this country get the maximum positive impact for the minimal resource input, regardless of whether public or private sector mechanisms or both are used? While we may not yet know how to do this, we have certainly learned what does not work well.

Product development is a creative act. Creating requires new thinking. Regulations place boundaries on thinking. You cannot bureaucratize creativity. Innovation and regulation are fundamentally incompatible, and it is not at all proven that classical regulation and enforcement are the only ways to protect the public interest and optimize both the safety and availability of medical products. It is an early 20th century paradigm that has grown into counterproductive ritual for the 21st.

Congress is an intellectually rich body with full access to all of the resources of an intellectually wealthy nation. Ensuring broad access to safe and effective devices is not an unsolvable problem. It is only a difficult challenge. What is wrong with our device laws and regulations and how they are implemented is yet another chapter and a very detailed one at that. After that history and diagnosis, we have an even greater challenge. We still have to develop the optimum therapy, or the national patient, patients in the aggregate, will suffer.

Our organization pledges its commitment to contribute constructively, fairly, and realistically to that process. Thank you for the privilege of testifying.

Mr. BARTON. Other than that, they acted appropriately.

We would now like to hear from Dr. Neil Kahanovitz. He is an orthopedic surgeon and a world-renowned expert in spinal surgery and lower back pain. In his pro bono work as a humanitarian, he has been awarded the Order of the Supreme Soviet Medal for personal courage, the highest civilian award in the former Soviet Union for his work in Russia and Armenia in the aftermath of the 1988 earthquake. He still participates in an exchange program with Russia on spinal surgery.

Dr. Kahanovitz attends Members of Congress, and members of the U.S. Supreme Court, and has recently organized the Center for Patient Advocacy.

Dr. Kahanovitz.

STATEMENT OF NEIL KAHANOVITZ, M.D.

Mr. KAHANOVITZ. Thank you, Mr. Chairman, and members of the subcommittee, for inviting me to speak today.

Despite the fact that I am, by training, a spinal surgeon, I am not here today to discuss my feelings or even voice my frustrations over the ongoing pedicle screw controversy. It is my belief that the pedicle screw issue merely represents a small tree in the midst of a large forest of FDA problems that continually challenge the very fabric of the time-honored doctor-patient relationship.

I distinctly remember my first days in medical school when knowing virtually nothing about the practice of medicine, our first lecture told of the sanctity of the doctor-patient relationship in which the ill and often frightened patient puts his faith, both physically and emotionally, in the hands of that physician, relying on that doctor's judgment and insight to provide the best medical care and treatment available.

For centuries trust and faith in the doctor-patient relationship has served us well. Unfortunately, outside forces are more and more frequently putting this long-standing relationship in jeopardy. Competent physicians are no longer guided in the quest for the best treatment and diagnostic options by what they perceive to be the most up-to-date medical care.

When making therapeutic and diagnostic decisions, the treating physician must not only weigh the merits of a drug or device on his or her beliefs of the clinical efficacy but ever increasingly on the potential medical legal implications of its use. Too frequently, the use of a device in any way other than specifically labelled by the FDA approval process opens the door for potential liability on the part of the physician. This is truly ironic since the proposed use of that drug or device may, without a doubt, be the most widely accepted and state-of-the-art use of that particular drug or device despite specific approval or labelling by the FDA.

In my written testimony, I have submitted a number of examples of devices which, although distinctly different in their complexity, illustrate this dilemma. These examples I have outlined as well as others illustrate the potential conflict that a physician must face simply because of the delays and indecision on the part of the FDA.

There is no greater frustration on the part of a treating physician than to know that the best and most up-to-date treatment cannot be made available or, more frequently, lead to potential medical legal implications because of the inaction and delay on the part of the FDA.

This intrusion into the doctor-patient relationship must not be tolerated by a government agency whose primary job is the evaluation of safety, not clinical practice. The American public demands and deserves to be protected from unsafe drugs and devices. As a physician, I rely on the FDA to ban any unsafe drug or device, but as a physician I must be allowed to practice medicine as I see fit. I must be able to provide, as a patient's treating physician, what I believe to be the most effective mode of treatment available without outside interference of the actual practice of medicine.

The FDA must go back to the basics. We, as Americans, rely on them to assess safety, and they should continue with this meaningful and worthwhile goal. They must, however, leave the practice of medicine to the physicians.

I have attempted to practice medicine during my medical relief efforts in the Soviet Union and other less medically fortunate countries around the world. American physicians are in an enviable position to be able to practice medicine with technologic advances never before thought possible. The FDA must allow us to continue to enjoy the greatest quality medical care ever known to mankind.

If patients cannot rely on their physicians to intellectually, morally and ethically provide the best quality medical care available, the sacred doctor-patient relationship will be lost forever.

Thank you.

[The prepared statement of Neil Kahanovitz follows:]

PREPARED STATEMENT OF NEIL KAHANOVITZ, M.D.

Mr. Chairman and members of the Subcommittee, thank you for inviting me to speak about my experiences as a concerned physician as they relate to the role of medical devices and the practice of medicine.

Physicians since the time of Hippocrates have followed his basic medical tenet: "Physician do no harm." Providing the best and most compassionate medical care that science has afforded has guided physicians through centuries of innovations and progress so that ultimately the patient could benefit from a long and healthy life as free from suffering and disease as possible.

Unfortunately, "Physician do no harm" is no longer a decision making process determined solely by the knowledge, insight, and education of the treating physician. Practitioners are no longer able to provide in all cases what has been, and more importantly what should be, the best and most current state of the art diagnostic studies and treatment devices. When making therapeutic and diagnostic decisions, the treating physician must not only weigh the merits of a device on his or her beliefs of the clinical efficacy, but ever-increasingly, on the potential medicolegal implications of its use. Too frequently, the use of a device (or a drug for that matter) in any way other than specifically labeled by the FDA approval process opens the door for potential liability on the part of the physician. This is truly ironic, since the proposed use of that device may without a doubt be the most widely accepted and state of the art use of that particular device despite specific approval or labeling by the FDA.

My colleagues in a diverse number of medical specialties have spoken of several examples of off-label uses of devices that illustrate this dilemma. One example is the triple marker screen. Although unapproved by the FDA, this non-invasive device which tests for three chemicals that detect Downs syndrome is considered the standard of care. A physician might be guilty of malpractice if this device is not used even though FDA has not approved it for this particular use. In the case of EP catheter and its use for cardiac ablation, the FDA approved this product for cardiac monitoring, but doctors discovered it could also be used to treat the heart tissue by removing diseased heart tissue with an electrical current which this device provides. This device became the standard of care but was not approved by FDA for that purpose until recently, some years after the accepted off-label use. Prior to approval of this use, FDA threatened to rescind all prior approvals which would have caused the removal of the device from the market because of off-label practices. The PSA (Prostate Specific Antigen) is yet another notable example of off-label use. FDA only approved PSA for monitoring. However, the American Cancer Society promoted this product for an off-label use. FDA finally approved the use for one company. Lastly, cementless hip and knee replacements devices for years were used off-label until they become approved.

Medical science cannot stand for this type of bureaucratic delay. The real victim is not the drug or device manufacturer, the physician or the hospital. There is only one real victim: the American citizen.

Medical science continues to develop devices which we thought impossible a decade ago. Patients should be receiving such technology as rapidly as it is being developed. Sadly, this is not so. Countless lives should have been saved and the quality of life for many others improved had the FDA acted responsibly and timely approved applications as directed by the Congress. Timely review and approval of new devices, particularly in the area of heart disease, will allow patients to lead far more productive lives. This is also true for approval of drugs in the area of cancer and

AIDS. Perpetuation of the bureaucratic mire will only result in unnecessary suffering.

No one with a conscience would ever want to experience another Thalidomide tragedy. The FDA continues to use this event as a shield to fend off any criticism of its bureaucratic process. There is not one single physician, manufacturer, politician or citizen in the United States that is advocating putting the FDA in a position to allow another Thalidomide tragedy. What everyone is asking is: "Why can't the FDA do what has been legislated by the American people through their representatives in Congress? Why must the FDA interfere with medical science and the ability of the physician to save lives only to protect its self-perpetuating bureaucracy?"

Implicit in this flawed bureaucratic process is not only the delay in new devices reaching needy patients, but FDA interference in the ability of the physician to practice medicine. The FDA never received a legislative mandate to police or even direct the practice of medicine, but that is exactly what it does.

The patient-physician relationship is in a tenuous state. This can be explained two-fold: 1) the FDA has not acted to clarify labeling controversies; and 2) the FDA intermingles efficacy issues with clinical decision making and practice. The off-label use of devices has placed the physician in a perilous position when faced with providing what should be the state of the art clinical recommendations while at the same time avoiding serious medical liability. The result of FDA indecision and inaction is that patients are not afforded the most current diagnostic and therapeutic opportunities. Timely action by the FDA for the most part will eliminate these mediolegal obstacles and once again allow the patient to receive the best and most appropriate care available.

This is not only a patient care issue. As the taxpayer funded budget of the FDA continues to grow, so does the cost of each new device that goes through the bureaucratic review process. The time and the cost of introducing new devices in the U.S. is greater than anywhere else in the world. As the costs of the review process continue, to escalate, there will be less enthusiasm and money devoted to the invention of new devices.

The critical question we must ask ourselves is: "Who is the victim of this bureaucratic travesty?" The answer is evident—all of us. Lives are being needlessly lost and the quality of life sacrificed by the FDA's bureaucratic morass, which steadfastly refuses to conform to statutory mandates for reviews. Perhaps the FDA should allow itself to come under the most basic of all the ethical teachings that has guided the practice of medicine for centuries and conform to the very essence of the Hippocratic teachings, "FDA do no harm."

Mr. BARTON. Thank you, Dr. Kahanovitz.

To introduce our next witness, we have the Honorable Steve Horn of the great State of California, one of Congress' own Ph.D.s who wrote his thesis on the way the Congress operates. We welcome Congressman Horn to introduce Dr. Yavitz.

Mr. HORN. Well, thank you very much, Mr. Chairman. I commend you and the staff for this exciting series of hearings that you are holding.

I have known Dr. Edward Yavitz for almost 2 decades. I met him first when he was a residency in residence at the University of California Medical Center in San Francisco, one of the great medical centers of the Nation. Then he moved to Rockford, Illinois, and, of course, he graduated from the Harvard Medical School, the distinguished school, so he has been in the East, the West, and now settled in the Midwest.

His peers have said repeatedly that he is an immensely skilled surgeon, ophthalmologist, and has the high respect of those in every community in which he has lived. So I am delighted to present him to the committee.

Mr. BARTON. Thank you for the introduction.

We would now like to hear from Dr. Yavitz.

STATEMENT OF EDWARD Q. YAVITZ, M.D.

Mr. YAVITZ. Thank you, Dr. Horn.

Chairman Barton, and members of the committee, thank you for allowing me to speak today about medical device approval by the FDA from the perspective of an ordinary Midwestern doctor.

I am Edward Yavitz of Rockford, Illinois. I grew up in St. Louis, graduated from Harvard Medical School and the University of California, and have been an eye surgeon in Rockford, Illinois, for the past 14 years. I have always been proud that I trained with the very best teachers, and I promised myself and my patients to keep up with the latest advances in my field.

But in the last 5 or 6 years, I am sad to learn about new surgical techniques and devices being used in Canada, Europe and Asia that are improving vision in those countries that I can't get here because the FDA is still reviewing them. I go to national meetings and ask to buy a device for opening up cataracts which is being used daily in England, and the salesman laughs and tells me it is only for sale in the free world, not the United States of America because the FDA hasn't approved it here yet.

There is a laser called the Holmium Laser which is being used today in Europe and Asia to reshape the front of the eye so that people over the age of 40 can read again without bifocals or reading glasses. The operation takes less than a minute, but it will take more than 3 years for the FDA to approve it here. I see several members of the committee wearing readers who will just have to wait.

Congress had the courage to create the FDA at the turn of the century to protect the American public. That job is certainly more complex today than it ever was. Medical devices are being created faster than the FDA can process them no matter how many dollars and people you give this agency.

Let me give you another example. In the 3 or 4 years it has taken the FDA to review one Excimer Laser, no fewer than six other designs of the same wavelength laser have gone to market outside the United States, each having advantages over the original design.

I was recently offered a 6-year-old model of the laser which the FDA is about to release to American doctors because the owner who lives in the Bahamas wants to buy a newer machine with improved features made by a competing company.

The root of the problem is how the FDA has interpreted the Safe Medical Device Act which Congress created in 1990 to establish a classification system for all new medical devices. Each new type of device starts out as a so-called "Class III" device, which requires a multi-year premarket approval procedure to prove to the FDA that the device is safe and effective. Well, so far so good, to maintain the highest standards in the world, we do have to test things, although if Congressmen only get 2 years to prove themselves safe and effective to their constituents, why should the FDA take any longer on a medical device.

But here is the real problem, I was told by a staff member of the FDA about their rule of four. Once the FDA gives its approval to a generic device, such as an Excimer Laser, your 1990 law forces them to keep all similar devices Class III even though a faster track with plenty of safeguards called Class II exists, until four different manufacturers go through the same multi-year PMA testing.

To make matters worse, the makers of each of these parallel devices cannot use the data that convinced the FDA that the first device of its kind was safe and effective. This is redundant. It wastes taxpayers' money, impedes competition, and allows the first company to get an approval, a marketing advantage it would not get on foreign soil.

We should encourage improvements to a basic design, not slow them down by treating them like a completely new device. If Congress did nothing more than get rid of this rule of four and require the FDA to automatically reclassify any premarket approval device from Class III to Class II as soon as it is approved, you would end the logjam without compromising safety, and free up the FDA to devote more attention to monitoring outcomes and performance of devices where they are being used by doctors like me.

In conclusion, I am not sure if one doctor from the Midwest with a little common sense can produce a change in an organization as complex as the FDA. I am not asking Congress to dismantle the FDA or rewrite the classification system that you drafted in 1990, just use it properly and efficiently so that many small, innovative companies don't take their ideas abroad rather than slowly hemorrhage to death in the hearing rooms of the FDA.

If I could have 1 more minute just to extemporaneously comment on what Dr. Johnston was saying, and Dr. Kahanovitz, about the micromanagement of the FDA of medical practice, the members of this committee need to understand that medicine is an art, and it progresses on a case-by-case basis, by trial and error often. Doctors use the medicines and the machines and devices that we are given in different way, and when we find something that works, we publish it, we discuss it with our colleagues, and that is how medicine goes forward. We do not need David Kessler telling us how far we should put the thermometer in.

Thank you.

[The prepared statement of Edward Q. Yavitz follows:]

STATEMENT OF EDWARD Q. YAVITZ, M.D.

Chairman Barton and members of the committee, thank you for allowing me to speak today about medical device approval by the FDA from the perspective of an ordinary Midwestern doctor. I am Edward Yavitz of Rockford, Illinois. I grew up in St. Louis, graduated from Harvard Medical School in 1977 and have been an eye surgeon in Rockford, Illinois for the past 14 years. I have always been proud that I trained with the very best teachers and I promised myself and my patients to keep up with the latest advances in my field. But in the last 5 or 6 years I am sad to learn about new surgical techniques and devices being used in Canada, Europe and Asia that are improving vision in those countries that I can't get here because the FDA is still reviewing them. I go to national meetings and ask to buy a device for opening up cataracts which is being used daily in England and the salesman laughs and tells me it is only for sale in the free world—not the United States of America because the FDA hasn't approved it yet. There is a laser called the holmium laser which is being used today in Europe and Asia to reshape the front of the eye so that people over the age of 40 can read again without bifocals or reading glasses. The operation takes less than a minute but it will take more than 3 years for the FDA to approve it here. I see several members of the Committee wearing readers who will just have to wait.

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The root of the problem is how the FDA has interpreted the Safe Medical Device Act which Congress created in 1990 to establish a classification system for all new medical devices. Each new type of device starts out as a so called CLASS III device which requires a multiyear Premarket Approval procedure to prove to the FDA that the device is safe and effective. So far so good, to maintain the highest standards in the world we have to test things—although if Congressmen only get 2 years to prove themselves safe and effective to their constituents why should the FDA take any longer on a medical device?

But here's the real problem. I was told by a staff member of the FDA about their "Rule of 4". Once the FDA gives its approval to a generic device it insists on keeping all similar devices CLASS III even though a faster track with plenty of safeguards called Class II exists—until 4 different manufacturers go through the same multiyear PMA testing. And to make matters worse, the makers of each of these parallel devices cannot use the data that convinced the FDA that the first device of its kind was safe and effective. This is redundant and wastes taxpayers money, impedes competition and allows the first company to get approval a marketing advantage it would not get on foreign soil. We should encourage improvements to a basic design, not slow them down by treating them like a completely new device. If Congress did nothing more than require the FDA to automatically reclassify any PMA approved medical device from CLASS III to CLASS II you would end the log jam without compromising safety and free up the FDA to devote more attention to monitoring outcomes and performance of devices where they are being used by doctors like me.

In conclusion, I am not sure if one doctor from the Midwest with a little common sense can produce a change in an organization as complex as the FDA. I am not asking Congress to dismantle or rewrite the classification system you drafted in 1990. Just use it properly and efficiently so that many small innovative companies don't take their ideas abroad rather than slowly hemorrhage to death in the hearing rooms of the FDA.

Mr. BARTON. I think we would agree with that.

The Chair is now going to recognize the members for questions. Mr. Sklar, when the FDA has been approached about this glucose sensor, their initial reaction is that the accuracy is not as it should be to be approved for use. Do either you or your wife have any comments about the accuracy of the glucose sensor as compared to the prick test that is in use now?

Mr. SKLAR. Well, generally, the word in the diabetes community is that none of these devices are very, very accurate, and that information essentially comes from the pediatric endocrinologists who participated in the clinical trials with these devices.

Again, once the first generation noninvasive glucose sensor is out on the market, I am sure there will be other sensors to follow which will become incredibly accurate with time, but for the time being we are fairly optimistic that the first generation works very, very well, and I think it is crucial to get the first one out there because innovation in the marketplace is what it is all about.

Mr. BARTON. What is the real world downside if, in fact, this new noninvasive device is not as accurate every time it is used? What would the result be to your daughter if there is a false reading?

Mr. SKLAR. Well, Chairman, I think we have to start with the basic premise that no device is 100 percent accurate, not even the current technology which is on the market which do work very, very well, and we are very satisfied with. I think this particular device would be very helpful because it works in a different manner. We certainly could even supplement the six or eight tests we do every day and fill in the blanks. Essentially every 4 hours, we are testing Bonnie, or every 3 hours, and in between those time periods we are guessing where her blood sugar is.

Mr. BARTON. The point I am trying to get at, is in the real world, since we don't expect 100 percent accuracy in anything. Even the voting record of Members of Congress we don't expect to be 100 percent. If this device were 85 percent accurate in actual use, if, in fact, it gave a false reading, the patient or the parent, in your case, would be able to see some symptoms and take remedial steps so that there wouldn't be a life-threatening situation, is that safe to say?

Mr. SKLAR. I think every insulin-dependent diabetic and their parents realize that if you get a reading that doesn't make any sense, the first thing you do is go back and test again, and certainly the simplest way to check if the noninvasive glucose monitor is working is to line up the two units, the convention glucometer and the new noninvasive monitor, and within a minute you would have a control and you could tell if both devices are producing roughly the same number.

Mr. BARTON. Okay.

Mr. SKLAR. Again, just to summarize, this device would be incredibly use for us, even, I believe it is as accurate or more accurate, but even if it was slightly less accurate, it still would be incredibly useful to us.

Mr. BARTON. Thank you.

Dr. Nobel, you painted a very persuasive picture of some of the problems. You didn't, unless I misread or missed some of your testimony, go in any detail on a proposed solution. Do you want to present a proposed solution for this panel to consider since you don't necessarily think we need to shorten the time. You seem to think the process itself needs to be reformed. Could you elaborate on that?

Mr. NOBEL. I think that if the process is reformed, the timing issue will solve itself. I do believe that the process has to take place in a far shorter time, but I don't believe that one can achieve that simply by outsourcing or adding resources. I think it is the process that has to be looked at. It is not terribly different than looking at process engineering in a manufacturing plant. If the process is wrong, speeding it up breaks the machinery.

Mr. BARTON. So what is one specific proposed change in the process that you would like to propose?

Mr. NOBEL. If you will forgive me, I am a physician, and I first like to make a thorough diagnosis before I suggest a form of therapy. It would be premature to suggest specific ways of speeding up the approval process without a more thorough understanding and conference with FDA personnel. I am not hedging, I guess I am saying I don't know——

Mr. BARTON. It certainly sounds like a hedge to me.

Mr. NOBEL. Okay. Well then, let me put it more specifically, I don't know enough about the internal processes for approval to suggest specific ways of dealing with it. I think that a large part of the problem is the value system within the organization, the fear of making a mistake, the fact that there is no penalty for saying no. There are a host of philosophical issues that have to be dealt with and value-laden issues, but the actual process of speeding things up, whether it is a paperwork flow issue, whether it is understanding——

Well, let me give you one specific example. Approaching the FDA on a 510(k) basis was a obstetrician/gynecologist who had developed a new in vitro fertilization needle, it had a different shape or curve to it. The common sense approach would have been to say, yes, well, it has a different shape to it, go ahead and market it, because how the shape is used is intimately related to the physician's skills and the ultrasonic mapping or visualization technique.

Instead, what the physician was told was, you have to do animal toxicity studies on the material. Well, this is a device that is in the body for a couple of minutes. The material is identical to that used in stainless steel needles for an awful long time, nobody else was asked for it. Why on earth would you repeat toxicity studies? It is just totally irrelevant. So the project was dropped.

It is the common sense issue that has to be addressed.

Mr. BARTON. Thank you.

The chairman's time has expired.

The Chair would now recognize Mr. Wyden of Oregon.

Mr. WYDEN. Thank you.

Mr. Sklar, first let me tell you that I have a 5-year-old little girl at home, and I can just imagine how frustrating and exasperating this is to you, and how much you want to get your daughter away from these frequent needle sticks. I wish we had the FDA here to give their explanation.

Mr. Chairman, I would just like to ask that the two of us inquire together as to what is going on at the FDA with respect to the problems of this device.

Mr. BARTON. Without objection.

Mr. SKLAR. I would be most grateful. Thank you very much.

Mr. DINGELL. Would the gentleman yield?

Mr. WYDEN. I would be happy to yield.

Mr. DINGELL. I think we ought to hear from the company. I think, Mr. Chairman, we have a problem here. We have the company's perspective; we have FDA's perspective. I think Mr. Sklar has made a persuasive case, and we ought to pursue this matter further.

Mr. BARTON. I think the former chairman has made an excellent suggestion and we will do that.

Mr. DINGELL. I would ask that we have both FDA and the company before us so that we can discuss it and find out just why it is that this product is not being approved more speedily. I think he made a good case.

Mr. BARTON. The Chair will make sure that we do it in the most appropriate fashion, but we will get both sides of the question.

Mr. WYDEN. I appreciate the chairman's willingness to do this, because I think not having the FDA here today in particular is sort of like having the O.J. trial without O.J., and I would really like to get to the facts and particularly to respond to Mr. Sklar. I don't think anybody can imagine how traumatic this kind of thing is for you, and I want you to get some good answers.

Mr. BARTON. I am not sure that O.J. would want to be compared to the FDA, so let's don't.

Mr. WYDEN. We will use our 7 minutes here in another fashion than further discussion of that. I want to direct this to the four doctors on the panel, because I think you all have really joined the issue here for us, and I want to take the time to walk this thing through slowly.

The FDA now has a public health mission to make sure that drugs and devices are safe and effective. That is current law. What you all have said is that the FDA is moving too slowly, and that it hogties patients, and companies, and consumers with its caution. My sense is that what you really want to do is set up a whole new world of risk assessment, where the FDA would back off on some of its requests, and I gather that companies and doctors would assume more risk with respect to unproven products.

Several of you have talked, for example, about relief from liability specifically, and on Capitol Hill now we have companies and physicians and others asking for specifically that.

My concern here is that we could be heading towards an antipatient trifecta where you have a situation where the FDA backs off, that is something that has been requested here, doctors and companies are immunized from liability, and the patient would assume all the risk. So my view is that the patient is in increased jeopardy under this kind of arrangement, and why don't we begin, if we could, with you, Dr. Johnston, as to how you think the system ought to protect the patient and the consumer from what appears to me a system that you all propose that would put that patient in more jeopardy.

Let's begin with you, Dr. Johnston.

Mr. JOHNSTON. Well, Congressman, I think your points are well taken, and I guess I would like to begin by reassuring you that the medical profession basically rejects devices and drugs and treatments that don't work. While the FDA's role has sounded, I think, very obstructive here today, there certainly is a role in the beginning of the evaluation of any new treatment or drug to establish its safety. Once that safety has been established, first by perhaps animal studies, and then by limited clinical trials by inventors, for example, then, as I mentioned in my testimony before, we pass along the information along a grapevine. We talk to each other a lot. So the things that work are quickly analyzed and absorbed by the medical community, and the things that are suspect or perhaps have undue percentage of complications are rejected and don't get much further than their initial clinical trial.

So I guess it requires a little bit of trust on the part of the consumer, patient, and the regulatory agency, the FDA, but basically the medical community is going to ferret out the things that don't work and will emphasize and jump all over the things that are innovative and do work.

Mr. WYDEN. I want to get our other physicians, but let me tell you what troubles me about this, and you seem like a very good, sincere individual. You are basically saying to the patient, trust us. You have patients who do not have expertise in the engineering of medical technologies and it just seems like the equation is imbalanced.

Let me get the views of the other physicians. Please, doctor.

Mr. NOBEL. With respect, Mr. Wyden, I am not prepared to grant the fundamental assumption that underlies your question. The problem is that the FDA's current processes do not assure safety and effectiveness in a balanced way, so comparing what we have now to what we could have is a little bit of a mysterious process to me.

We investigate on the average a medical device injury or death to a patient probably on the order of 3 or 4 times a week. That is probably more than the FDA does. Every one of these injuries or deaths is caused by an FDA approved device. I rest that part of my case.

The greater problem is really user error, more than 50 to 60 percent of injuries and deaths are caused by user error. The FDA has deemphasized the issue of user error and user education over the past couple of years instead of increasing it in response to the common observation that this is where the bulk of the issue lies. Perhaps because it is easier to regulate five or six thousand manufacturers than the behavior of four or eight million—depending on how you look at the numbers—health professionals.

While we are having this very cogent discussion, the courts, which are totally unconnected with this process, are weakening patient protection by granting, in effect, sovereign immunity to companies that have produced defective devices that have injured people, and they do that through the preemption process. Since it is an FDA approved process, it is a regulated industry, the company is not responsible for the consequences, and I think that that issue is terribly damaging to patients, not simply from an economic point of view, but because it eliminates pressure on industry to be more virtuous.

This is a very, very complicated arena in which you simply can't say, if we do this, will it harm patients, because while we are doing that, there are six other variables and an extra-regulatory activity that are taking place that shift the sand.

Mr. BARTON. Could we have the other two doctors respond briefly to the question before we recognize another questioner.

Mr. KAHANOVITZ. I think that you have to go back to the questions you asked about who is assuming to take on the risk in the safety, and I can honestly speak back to my early years as a physician, I took care of Thalidomide patients. I mean, I took care of the tragedy that resulted from that drug, and I can honestly tell you that no one at this table, and I can probably speak for everybody in the medical profession in this country, wants to see that ever, ever happen again.

But I think that you need to go back to the two basic issues that affect me as a physician trying to give my patient the best quality care. The first thing is, if the FDA would only go back and do what has been legislated within those timeframes, which is produce safe and effective drugs and devices within that 90 and 180-day timeframe, I think a lot of these problems would go away.

The second thing, which is making things very difficult and complicated for a physician to practice, is the dilemma that surrounds off-label use. Off-label use is now more and more frequently being interchangeably called "illegal" use. One only needs to look in the area of orthopedics and total joint replacements. The latest version of the total joint, the one used without cement, has been approved for osteoarthritis patients, the garden variety type of arthritis, but there is nowhere in the labelling that says that it has been approved for a patient with rheumatoid arthritis, and you can't tell me that there are not millions of people out there with rheumatoid arthritis who can now walk pain-free because they have had a total joint implanted. But many people, on the other hand, would say that this was done illegally as opposed to off-label.

This controversy needs to be cleared up so that we, as physicians, can practice medicine without the off-label implications guiding our judgment.

Thank you.

Mr. YAVITZ. I want to go on the record also as saying that I think that the premarket approval process is a very thorough and painstaking process, and I think that with some devices you may need more than 180 days. This Excimer Laser, for example, may affect 20 million Americans who want to get rid of their glasses, and maybe it is correct that it took longer than 180 days to look into it, and the FDA has been so careful and painstaking on the PMA process, I say, why should they have to do it over and over again just because another manufacturer comes along with a similar device. That is why I think the rule of four should be reduced to a rule of one, automatic down classification to Class II before you give approval to a generic device.

I will give you one example, the Excimer Laser was applied for by Summit Company way back when using a 5 millimeter wide zone. Now the doctors in Canada quickly discovered that 12 percent of the patients had so much glare after this treatment using that zone that they decided not even to have their other eye done. They were very unhappy with the results. So they widened the zone to only 6 millimeters, just a one millimeter difference, and that took care of the problem.

When the FDA approves this laser later this year, which they intend to do, I think, we will have to be using this laser at a 5 millimeter zone because that is the data that was given to them. The company itself went to the FDA and said, hey guys, we made a mistake, can we use it at 6 millimeters, it is going to make a lot more people happy. The FDA said, not unless you want to start over again and give us data for 3 years using a 6 millimeter zone. That is just micromanagement, and that is not common sense.

Mr. BARTON. Mr. Wyden.

Mr. WYDEN. Mr. Chairman, just very briefly. I want it understood that the ideas you are making with respect to the approval process and shortening the time periods, your comments about illegal use, these are things that Democrats and Republicans are going to agree on. What I am troubled about is this idea of allowing off-label use and putting all the risk onto the patient around the idea that they ought to just trust physicians and companies. We will discuss this more, and I thank all of you for your excellent testimony.

Mr. BARTON. I thank the gentleman from Oregon.

The Chair wants to let the distinguished gentleman from Michigan know that the company that has this device pending before the FDA was invited to attend and chose not to do so for fear of retribution. They did not want to antagonize the FDA, so they did not want to come forward.

Mr. DINGELL. Will the gentleman yield?

Mr. BARTON. Yes, sir.

Mr. DINGELL. Was that the company referred to by Mr. Sklar?

Mr. BARTON. Yes, sir, the one with the application pending.

Mr. DINGELL. Maybe I can give the gentleman who is now the chairman of the subcommittee the firm assurance that nobody dared take action against any witness who appeared before this subcommittee, and I would not tolerate that kind of performance by FDA or anybody else.

Mr. WYDEN. Would the gentleman yield?

Mr. BARTON. I would be happy to. I just wanted to put that on the record because we had made an attempt to do exactly what the distinguished gentleman from Michigan indicated.

Mr. WYDEN. If the gentleman would yield to me, this is the first time that I have heard about this. I want to assure the gentleman that that is absolutely unacceptable to me. I would like to work, again, with you and Mr. Dingell and Mr. Bliley to followup this matter, because that is the kind of thing that when Chairman Dingell chaired this subcommittee was absolutely unacceptable.

Mr. BARTON. I understand.

Mr. WYDEN. I think it is another bipartisan tradition that ought to be continued.

Mr. BARTON. I understand.

Mr. DINGELL. If the chairman would yield again. It is enormously difficult for us to get to the bottom of these concerns. I think Mr. Sklar has given us a very legitimate complaint, one which I think we could pursue. I think we could have FDA up here, but I think that we cannot get the full picture simply from having FDA up here.

Mr. BARTON. I agree. I concur with the gentleman's assessment. I just wanted him to know on the record why the company wasn't here.

Mr. DINGELL. I don't want my comments to be construed as critical of the Chair. They are, in fact, not. I think that if we don't get to the bottom of these things, we are going to confront problems where the records of this committee will tend to indicate one thing when, in fact, the result might be quite different. I want to hear from FDA and I want very much to hear from the company.

Mr. BARTON. I agree with that.

Mr. DINGELL. And if there should be any action taken against the company, I want to know about it forthwith so that we can commence dealing with that in the most forceful fashion.

Mr. BARTON. I share the gentleman's assessment and concern.

Lastly, I would like to indicate that you said the gentleman, Dr. Johnston, was trustworthy and sincere. That is obvious because he is from Texas. I mean that is a given.

The Chair would now recognize the gentleman from North Carolina, Mr. Burr.

Mr. BURR. Mr. Chairman, thank you.

Let me just, if I could, for a second continue with what Mr. Dingell has discussed. Mr. Yavitz, in your years of experience, are there a lot of companies out there that do not press the issue of approval with FDA because they are concerned with retribution?

Mr. YAVITZ. Well, I do not represent any companies, so I don't have an intimate knowledge of whether companies would be worried about retribution or not, although I do know of one example of a device, it was actually a material that we could have used to put inside of the eye during eye surgeries which would allow the inside of the cornea, the front of the eye, to heal itself and avoid more major surgery such as a corneal transplant, and I was involved in that study. Unfortunately, the FDA decided to make it more difficult for that company to produce it, and they withdrew the product rather than anger—at least that was their explanation to me—rather than anger the FDA.

Mr. BURR. So we are not talking about a single experience here?

Mr. YAVITZ. No. I think companies very much tiptoe around the FDA because they realize the power that they do have. They don't seem to follow the rules that you have set up for them, the timelines, and they very much can micromanage medicine, they know they can, and they get away with it.

Mr. BURR. Dr. Nobel, as a physician and really here representing a nonprofit, do you feel Mr. Sklar should be legitimately concerned about the 390 plus days that this noninvasive glucose sensor has been under review?

Mr. NOBEL. I think that you have to examine each device, each review process, each approval chain independently because these devices are enormously diverse, and what is required to clear one device may be irrelevant to another. It is very much an individual issue.

Mr. BURR. So using the example that, I believe Dr. Yavitz used, about a laser that went to a second generation and possibly a third generation, prior to approval of the first generation, should the FDA not use the research of the second and third generation that is already out there?

Mr. NOBEL. Yes, I agree with your proposition. Furthermore, I would like to absolutely emphasize that the public debate is not a fully honest one. The manufacturers, as a group, if there is any general characteristic you can apply to this, are terrified of the FDA. They will not come forward in public debate. They can be shut down and destroyed in a twinkling of an eye on a minor good manufacturing practice inspection documentation problem. Don't believe that if you grant them immunity you are still going to hear the truth. It is a little like going to the principal's office and being assured that the school bully is not going to beat you up. If you don't escort that kid home, you are not going to get the truth.

Mr. BURR. Let me go back to some of your comments. You stated in an answer to a question just a minute ago, "FDA process does not assure safety." "The approval process is deficient." "FDA needs to drop the cookbook method." "FDA should be a full participant in change."

I know that you were not specific with the chairman's question of specifically what do we do, but let me ask you this, is the FDA making any attempt to change or acknowledge that there is a problem in the process?

Mr. NOBEL. I hate to give you a yes and no answer, but let me explain each side, if I may. There are active efforts within the FDA, there are certainly active efforts in the revamping of government to reexamine how the FDA operates and how it does its job, and all that is to the good.

But there is a second problem. The fundamental organization culture of the FDA is probably congenitally incapable of admitting it has made a mistake. It is almost an inborn error genetics.

Let me give you a very specific instance, because I am not really a waffler.

Mr. BURR. Very briefly, if you would.

Mr. NOBEL. When we got into a technical contest with the FDA over the defibrillator previously discussed, I called one of the senior FDA officials at home without the interaction with that person's subordinates which tends to distort how information is provided, and I said, if we were to demonstrate beyond a shadow of a doubt, 100 percent level of confidence, that the FDA was technically wrong, would you be able to admit that you made an error. I quote the precise response, "There is no precedent for such an action."

That is much of the problem. If you don't learn from your mistakes, if you don't learn from experience, you can't get better.

Mr. BURR. Let me ask Dr. Kahanovitz. You said, "leave the practice of medicine to physicians." Let me just ask you, does the FDA listen to physicians' input, their experience, or their suggestions?

Mr. KAHANOVITZ. I think that there is no question, and I have given testimony before the FDA in years past on various products that are going through the FDA process, and the panels at that level, no question, listen to what the physicians have to say.

I think it goes beyond specific projects, specific devices, specific drugs, to the ultimate bureaucratic control of the entire process, so that they may listen to me on a specific drug or device, but I am not sure they are listening to the message of the doctor trying to take care of the patient in an overall much more global perspective.

Mr. BURR. I appreciate everybody's response about the physician-patient responsibility that each of you have.

Let me just go over to Dr. Johnston just real quick, and I will try to wrap it up. Your testimony said, the spine is essential to life, true?

Mr. JOHNSTON. Well, I think we would be in bad shape without one.

Mr. BURR. When the spine is injured by trauma or disease, can that be life-threatening?

Mr. JOHNSTON. Certainly.

Mr. BARTON. Mr. Burr, can you summarize?

Mr. BURR. Yes, sir.

Is the objection that the FDA has with your specific device that you have talked about with the device itself or the way that you are connecting it?

Mr. JOHNSTON. That is difficult to say because——

Mr. BURR. Or do you know?

Mr. JOHNSTON. I don't really know because, as I indicated in the——

Mr. BURR. You made the statement, though—just 1 more second, Mr. Chairman—that you advised some patients that there is a nonapproved way to attach it, and I guess in some cases they say, go ahead and do it, you are the doctor; is that true?

Mr. JOHNSTON. That's correct.

Mr. BURR. Who is liable?

Mr. JOHNSTON. I guess I am.

Mr. BURR. Does that raise your liability insurance?

Mr. JOHNSTON. It is already sky-high.

Mr. BURR. Have you been sued?

Mr. JOHNSTON. I have, yes.

Mr. BURR. Do you know of any case where an FDA approved product——

Mr. BARTON. Let the record show, most of Dr. Johnston's patients, as I understand it, are charity patients; is that correct or incorrect?

Mr. JOHNSTON. None of my patients are charged for care.

Mr. BARTON. Yes, they are not charged.

Mr. JOHNSTON. Anybody still can sue.

Mr. BURR. Anybody who would like to answer as far as the physicians are concerned, is there a case where there is an FDA approved product where we found that it actually shouldn't have been approved and a patient has turned around and sued the FDA?

Mr. NOBEL. I don't know of any cases where a patient can turn around and sue the FDA. I don't think such a thing has ever happened. I will talk to the FDA attorneys.

Mr. BURR. Thank you.

Mr. BARTON. Thank you.

We are now going to go to Mr. Klink, if he would care to ask some questions.

Mr. KLINK. Yes, I would.

I would like to followup what Mr. Burr was saying. Your testimony, Dr. Nobel, has intrigued me, and I appreciate your presence as well as that of the other witnesses.

Getting back to this cookbook methodology of the FDA, let me start at the farthest end of the extreme, would we be better off if we worked toward a system in which the FDA was not involved at all in making decisions about the safety and the efficacy of these devices?

Mr. NOBEL. No, sir. I think we need an effective FDA, not the disappearance of an FDA for these functions.

Mr. KLINK. I don't know exactly how to phrase this question, so beg that you will bear with me. On one hand, you talk about the fact that we can't use cookbook methods, that we tell people too much how to think and how to follow through the process, and we need to, I think you seemed to say, and I don't want to paraphrase you, I will let you do that yourself, that we have to give them more latitude. But on the other hand, you talk about the fact that 50 to 60 percent of the deaths are caused by user error on the other end.

Those two thoughts seem to be diametrically opposed. If we aren't precise in how we do the testing, if we aren't precise in how we tell the users how to use these devices, then we, in fact, have those errors that ultimately can lead to death or other difficulties. Am I clear on what you have said, and let me just ask you to comment?

Mr. NOBEL. Perhaps I wasn't clear. I think there are several different issues. Even if there are good manufacturer's instructions, even if the FDA has approved a device, even if the processes in Rockville were perfect, you will still have a significant number of injuries and deaths due to user error. It is just the nature of medicine, the nature of dealing with large numbers of people. You can make it better, but you can't eliminate it.

With regard to discretionary, I guess what I am asking for is that the FDA have more discretionary capability to think and adjust individual circumstances and devices to a common sense framework, but less power. There are two different things. In a sense, what Congress has done has given to the FDA the power of all three branches of government, regulations have the force of law in the legislature, the executive investigation and prosecutorial power exists within the FDA, and there are an awful lot of judgment or judicial types of activities. So what they need is more discretion to think and more flexibility in dealing with individual devices, and less power because it leads to abuse and arrogance, and if those things appear incompatible, then perhaps that is the essential dilemma of government, and I have no answer.

Mr. KLINK. All the easy stuff was done way before I got here, I am sure.

Let me just go round this again. In essence, your quote about the question to the person at the FDA, would they admit that they had made a mistake, they thought they had made a mistake but found out they were wrong, I guess. My question here is, you are talking about giving more discretion to someone who does not appear to be showing good judgment.

How can we as legislators, and maybe we are going back and taking a bite out of the same apple, I don't know, but how can we as legislators help these people to develop good judgments just by simply taking power away from them, being less restrict of them? I don't understand how we can do that.

Mr. NOBEL. Perhaps we can't, but I think we do have to review the approval processes, the postmarket surveillant processes. There are many things that are being done that don't need to be done. It is lack of focus and lack of priority.

For example, I am not sure that user reporting requirements as part of postmarket surveillance serve any value whatsoever. While it might seem counterintuitive, if we had a lot of time, we could certainly explore why. For one thing, we get a lot of information on a voluntary basis. For a second thing, what it has done is shift energy and priorities to computer exercises in data acquisition rather than energy into analysis and correction. You can go into any one of these things.

With regard to approvals, let's take something as simple as the sensor pad, the subject of a lot of discussion publicly. It is the device which is supposed to amplify the sense of feel during breast self-examination by women. For me, that is a 2-minute no brainer rather than a 9-year waiting period for approval. The reason it is a no brainer is that all you have to do is say to the company, we want some instructions with your product, and the instructions are, examine your breasts with this pad, do it with your fingers as is recommended by the cancer society, do it with soapy water on your fingers, because no one really knows which of those two is best, get your mammography on schedule, get your ultrasonography if the physician asks for it, have the physician do the annual or appropriate interval examination and, by the way, there is a card with this product, and check of the method, any of six methods, that first finds a lump that is confirmed by a physician, and in 6 months you would have the answer to the question of whether or not that device works better than the other methods.

This is what I mean by a common sense approach, and the rules and the books and the regulations and the means of approval things don't permit this type of common sense approach.

Mr. KLINK. Then, doctor, let me ask you this, we have heard a lot about developing an underwriter laboratory type of private entity out there rather than the FDA. Is that the answer? Do we take a private entity so it is outside the government, you talked about giving less power to the FDA, if they have less power, the power has to be transferred somewhere else, it doesn't just go ahead, and if you do that, we are talking about treating medical devices just like toasters, or lamps, or ceiling fans.

Mr. NOBEL. I would not support privatization of the approval process. Some aspects of it are already privatized, that is, somebody has to do the clinical studies that are brought to the FDA. Someone has to do the basic groundwork.

I don't know how to respond more effectively to the question at this time. If you simply privatize a process, as it exists today, you will create a mirror image private bureaucracy to the FDA bureaucracy. It is the processes that have to be examined, they have to be examined in specific case histories to see where they led us down the wrong trail, why things took so long, and then we have to come out of that and generalize about broad improvement of the processes. But this is a very narrow and specific area that is hard to deal with with generalizations.

Mr. KLINK. Mr. Chairman, if I could ask unanimous consent if any of the other witnesses might have a brief comment?

Mr. BARTON. Without objection, a brief comment.

[No response.]

Mr. KLINK. I guess not.

Mr. BARTON. That is brief. We appreciate that.

The Chair now recognizes the gentleman from California, Mr. Cox.

Mr. COX. Thank you very much. I am delighted that Congressman Klink has just asked the question that he has because I think that is where all of your testimony is leading us.

Has anybody here seen The Madness of King George, if you think about the progress that through 5,000 years of human civilization medicine has made just recently, it is extraordinary, and it is the source of our problems.

The King of England in that movie saw the extraordinary and ridiculous medicine treatments that were available to the King of England just at the founding of our country, and most of the change that has occurred between then and now has occurred in the last several decades.

When I was in high school physics class, I used a slide rule. When I went to graduate business school, I bought my first calculator for $75, and the most complicated arithmetic function it performed was the calculation of square roots.

Dr. Yavitz, I think, put a very fine point on it. One sentence in his testimony sums it up. He says, "Medicine devices are being created faster than the FDA can process them no matter how many dollars and people you give this agency." I think that is the problem. We have a Nation of over a quarter-of-a-billion people, many of our high-tech bio-tech companies are started up by a few doctors with a good idea of how to build a better mousetrap, and if we have a centralized agency in Washington that acts as a bottleneck for all innovation, it will come to a halt.

Dr. Yavitz, do you want to respond?

Mr. YAVITZ. That is because they do not recognize similarities between products. They see each manufacturer as a separate entity, a completely different product. They are not just interested in the safety and effectiveness of a device, they are starting to get involved in the profitability of a device. They are worried that the first four companies that go through this 3-year PMA process and spend millions of dollars are going to call them on the carpet because the fifth company gets to go through on an easier track using a Class II classification.

Well, it is a faster track, yes, but it is no walk in the park. It is not a water slide. They still have to submit to special controls. I am just saying that when a laser is approved, or a certain type of device is approved, and the next company comes along with something similar, use your common sense and say, you know, it is the same device, it is the same wavelength, guys, this is Class II, it is no longer III. When they want to change by one millimeter the treatment zone, why make a Federal case out of it.

Mr. COX. I don't think there is much question that we can, at the margins improve through minor changes such as you are suggesting dramatically what goes on at the FDA, but I also think we need to take some lessons from things that, for an example, Dr. Nobel is bringing to our attention that the European Union has studied our regulatory structure and rejected it, that it doesn't necessarily make sense as it is designed.

I wonder whether or not, if we take your advice, Dr. Nobel, and we accept at the outset that we are going to redesign the regulatory structure so that we are no longer regulating the entire industry, regulating individual doctor-patient behavior, which is what Dr. Kahanovitz is so concerned about, and I know, Dr. Johnston, that was your testimony as well, if we make that initial step, then does it make sense through statutory delegation of regulatory authority to give nongovernmental testing and reviewing laboratories, who would have the civil liability which, our colleague now departed raised, the FDA does not have, give them that authority so that we can get these things studied and approved much more quickly.

Anybody who would like to address that on the panel, I would ask you for your response?

Mr. NOBEL. I think it is an option that should be explored and evaluated. I am not prepared to say it will work better today because I am very concerned about simply transplanting an FDA set of concepts and regulation to the private sector. They will probably come to the same obstacles.

Again, it gets down to the very narrow issue of specific types of technology. It gets down to why isn't experienced people applying some common sense solutions, and I don't know how to make that happen in a regulatory framework which tends to depend on cookbooks.

I would also be a little cautious about the European Union model of regulation because you have to realize that they are at the very early part of the curve in the development of regulation. They don't have formal postmarket surveillance systems yet. Their system has the potential to grow as rigid as ours does over a similar period of time. So I am not sure that I would automatically jump for that kind of solution. I probably wouldn't.

Mr. COX. So you would give them high marks for having studied our system and recognized its flaws, but low marks for avoiding the same problems for themselves down the road?

Mr. NOBEL. I wouldn't give them low marks yet. I would wait and see how they respond to the challenges that they really haven't yet confronted.

Mr. COX. Dr. Kahanovitz, I inferred from your testimony that based on your experience helping Russian earthquake victims that even the infamous Soviet bureaucracy was less of an obstacle for the practice of medicine than the FDA's regime, what is your response?

Mr. KAHANOVITZ. I think if you put it in Russian terms, that the FDA really needs to be the safety police. They need to be the safety police, and not the clinical practice police. I think what Dr. Nobel said, not directly, but during his last few comments, really kind of brings it all to a head. No matter how good the FDA does their job, there will still be deaths and suffering due to whatever device or drug they have deemed safe, but that is not a reflection of the FDA, that is a reflection of clinical practice of medicine, which is purely and, unfortunately, today still and art. It is not an exact science.

Most of the doctors out there do things in good conscience, and I would hope that that would continue forever, but no matter how well intentioned you are, you are always going to have problems and complications. But the FDA can't be the policing force of clinical practice. I think if they pull back and go back to safety and efficacy, a lot of the regulatory bureaucratic delay could be eliminated.

Mr. BARTON. The gentleman's time has expired.

The Chair now recognizes the gentlelady from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman.

Once again, to each of the members of the panel, hearings are obviously designed so that we can learn something, and sometimes I wonder what is coming toward us from those that are trying to be instructive. I have learned a great deal from each one of your today, and I couldn't mean that more. It has been quite instructive.

There is more than one physician on the panel, so whomever would like to speak up on this, I welcome your response. Companies in California have developed innovative devices that help patients with third or fourth stage congestive heart failure, helping them to survive and lead lives that are longer, that are less painful. In at least one instance, the device is approved for use overseas but remains mired within the FDA in this country. It is a complaint that has come to me from my constituents and their first-hand experience.

What concerns me is not so much the fact that the device has not been approved, but that the FDA apparently lacks any kind of mechanism for fast-tracking and reviews of these types of devices. I understand that the FDA does attempt to fast-track AIDS drugs and some cancer therapies.

So from the perspective of a physician, in your view, can they do a better job of identifying promising or important devices, or does the burden of that responsibility still rest on the companies, and then what should be within the FDA in order to ensure a timely review process? I hope my question is clear. It is hard when the bells are ringing. Does anyone want to take that on?

Mr. KAHANOVITZ. I think it goes back to what Dr. Nobel said very succinctly, it is common sense. I mean, if there is a device or a drug that comes across the FDA desk and it clearly can save lives, let's say it is a new AIDS drug, or this new AIDS vaccine, I would certainly hope that somebody would have the foresight to say, hey, this is something that we have to look at today.

Mr. BARTON. If I could interrupt just a second, we just had a bell. There is a 15-minute vote on the floor moving the previous question, which is expected to be followed by a 5-minute vote on the rule.

We will let Ms. Eshoo finish her testimony, unfortunately then we are going to have to take short break to go over and vote, and then we will reconvene at 12:35.

Ms. Eshoo.

Ms. ESHOO. But I think you have to get back to what he said was basically common sense, and one needs to be careful about looking at the figures because what the FDA says has gone from a 6- to a 3-month delay needs to be looked at a little more specifically as to when that was filed, and what is lying around someone's desk for 6 months waiting to get the paperwork in, either on the company's behalf, the doctor's behalf, or on the FDA just letting it sit there, that all needs to be put into the equation of how long has this taken for whoever is at fault to get through that FDA process.

But I think the basic answer to your question is, somebody has to have some common sense.

Thank you.

Mr. DINGELL. Would the gentlelady yield?

Ms. ESHOO. I would be happy to.

Mr. DINGELL. Mr. Chairman, I have to leave, first to vote, and then to do other things this afternoon. Could I ask permission of the Chair and ask unanimous consent that I be permitted to submit questions in writing to the panel members for them to respond to for purposes of the record? Would that be in order, Mr. Chairman?

Mr. BARTON. Without objection, it would be in order.

Mr. DINGELL. Thank you, Mr. Chairman.

Ms. ESHOO. Mr. Chairman, may I ask the same so that we can get over to the floor because I do have several questions, and I know the time for us now going over to the House floor is brief, but I want to say thank you, again, to each one of you.

Dr. Nobel, you I think are really a nobel man, and I have several questions that I will get to you.

Thank you, Mr. Chairman, and thanks again to the witnesses.

[The questions, and responses to same, appear at the end of the hearing.]

Mr. BARTON. Thank you.

The Chair would indicate, I talked to Congresswoman Furse, she is also going to submit some questions in writing for this panel. Mr. Greenwood is not here, and I will ask him to do the same.

So we are going to go ahead and excuse you gentlemen, so that when we reconvene at 12:35, we will reconvene with the second panel.

So you gentlemen are excused, and the committee does appreciate your testimony.

We will be in recess until 12:35.

[Brief recess.]

Mr. BARTON. The subcommittee will come back to order.

We would now like to hear from our second panel. We have Dr. Arup Sen, Dr. Richard Ashman, and Ms. Gallagher.

We appreciate your indulgence in allowing us to go to our constitutional duty to vote. I think, if you are aware, that this subcommittee is an investigative subcommittee and, as such, it has had the practice of taking testimony under oath. Do either of you three oppose testifying under oath?

Mr. SEN. No.

Mr. ASHMAN. No.

Ms. GALLAGHER. No.

Mr. BARTON. Good.

You should also be aware that the rules of the House and the rules of this committee allow you to be advised by counsel during your testimony. Do either of you so wish to be advised by counsel?

Mr. SEN. No.

Mr. ASHMAN. No.

Ms. GALLAGHER. No.

Mr. BARTON. If you would stand up, please, and raise your right hand.

[Witnesses sworn.]

Mr. BARTON. We want to welcome you to the subcommittee. We are going to first hear from Ms. Ali Gallagher. She is an attorney, a nurse, and a nurse practitioner who has been involved in the health care industry for a number of years. In 1987, she did a postdoctorate fellowship in the office of the Honorable Dick Gephardt, who is now the minority leader. She was head of U.S. Medical Products last year and testified before this committee during the user fee hearings.

Her company, which was a small start-up medical company has been sold since that time because of delays by the FDA in approving one of her devices that her company was manufacturing. This device, an orthopedic hip and knee replacement device, was much less expensive than other products that were already approved, and because of the fact that the FDA would not approve her company's device for over almost a year, she had to sell the same equipment in Europe. In fact she sold over a thousand of these devices.

Ms. Gallagher.

STATEMENTS OF ALI GALLAGHER, U.S. MEDICAL; ARUP SEN, Ph.D., HEALTH TECH DEVELOPMENT, INC.; AND RICHARD B. ASHMAN, Ph.D.

Ms. GALLAGHER. Thank you.

My name is Ali Gallagher. I am the founder and former Chief Executive Officer and Chairman of the Board of U.S. Medical Products, a company based in Austin, Texas. U.S. Medical, as you said, is involved in the development of orthopedic implantable hip and knee devices. This same week 4 years ago, I started this company, and 2 months ago, after lengthy and costly delays at FDA, I lost the company to investors specializing in buying up distressed companies.

I want to share my recent experiences with this committee, and thank the members for holding these important hearings. What I have to say is important because it affects our economy, and because it preserves or weakens the health of the public.

My words are not as important as the job you have as legislators because maintaining the status quo today at FDA benefits no one. I testified before the Subcommittee on Health and the Environment in July 1994 in support of the Medical Device User Fee Act. My reason for doing so was to put a face on small business and tell the committee that efforts to improve the review process were critical to the survival of many small businesses.

I detailed for you then my company's story, a company formed to provide comparable quality medical products at a responsible price, and a company that recognized an opportunity existed to bring these highly featured products to market at a cost substantially lower than the list price of its competitors. We believed we could be innovative, aggressively challenge the competition and, most importantly, gain the FDA approval within the 90-day statutory time period. After all, we were not reinventing the wheel. We were positioning ourselves to be substantially equivalent to the leading products to the market, improving them wherever possible, and then lowering the price on items that were now costing our hospitals in the U.S. on average an amount equal to one-half of their total DRG reimbursement payment.

In 1991, when we began, the review determinations were made well within the 90-day time factor. We planned for this in our business and submitted our first premarket notification of 510(k) on a bipolar. For the committee's information, you can't sell too many bipolars because you need a hip stem to put them on. We filed at that time for our hip stem. We received the bipolar application on day 106 and shortly thereafter submitted the total hip. Then we waited.

After 1 year, we were still waiting for product marketing approval. We had to go abroad to survive. Indeed, but for the product acceptance and sales in Europe—and in our first year in sales in Europe, we sold $1.6 million—we would not have been able to continue as a going concern. In June 1993, still precluded from selling our main products in the U.S., I accepted our local Chamber of

Commerce's Exporter of the Year Award, and then proceeded to layoff one-half of our workers in an attempt to wait out the review process.

One month after these layoffs, 413 days after our submission, we received FDA approval on our hip system, and we hired back key people and we began again in earnest to grow the company.

It is important to point out that it was never an issue for us as to whether we would ultimately receive FDA approval. Our products, we knew, were of the same materials as previously approved. We had passed the same testing as to cyclic fatigue properties, anti-levirate requirements as what was already on the market, and we were, in fact, designing our products to be substantially equivalent to the predicate products being implanted prior to 1976 as per the statutory definition.

We were not asking FDA to allow us to work in new technology. These improvements centered around instrumentation improvements or various locking features necessary for intraoperative assembly of the device.

The medical device industry, especially with metal products, is capital intensive and capital needs run exceedingly high. Inventory turnover is averaged about one term per year. Our search for capital was never ending and was complicated by the delays at FDA. This unpredictability coupled with the regulatory slowdowns and the uncertainty of health care reform caused a chilling effect on private investment money. Even venture capital money dropped 34 percent in 1993.

According to a recently released report from the Health Industry Manufacturing Association, 51 public offerings generated $1.9 billion in investment money for medical device companies in 1992, and in 1993 that fell to $628 million. As of June 1994, when I went public, U.S. Medical and 11 other companies with a total of 12 public offerings generated only $222.5 million.

By the time we went public, we were already delayed over a year for our knee approval. We were still left with no meaningful way to gauge the approval time, or realistically plan for the knee production and without the knee our flagship product, hip sales, were negatively impacted because distributors and hospitals wanted companies with a broader range of products. Our knee remained in a black hole at FDA despite demand from our hospitals for an affordable, high-quality product that could have been made available.

Despite lower cost of product equivalents, we were precluded from selling to more than one-half the world market—the U.S. is one-half the world market—by a Federal agency unable to meet the task at hand, by a Federal agency that had no way of immediately responding to small businesses put into a crisis situation because of the delay times.

Our knee approval finally came in the third quarter of 1994, almost 500 days after submission. The expense of these delays in product review forced us, again, to be searching for dollars and funding sources were even scarcer. So after 4 years of building a company that was to bring savings to the hospitals it served, bringing its patented product improvements to the patients and surgeons using our products, we raised almost $7 million, about half from small private investors and half through the public offering, after receiving $2 million in revenue, gaining product approvals on a hip and knee line, obtaining international contracts in six countries, I accepted the fact that the company that I had built was essentially now going to be owned and controlled by an outside group of investors in the business of acquiring distressed companies, and I thank them for hopefully continuing what we have started.

Mr. Chairman, this dream of entrepreneurship and of innovation in the U.S. is seriously threatened because the companies noted for breakthrough innovation, the small start-up companies, are the ones who can least afford the increased costs associated with product delays, and 75 percent of the 11,000 members of the health care technology industry are such small businesses employing fewer than 50 workers. I cannot help but think that unless the regulatory thicket at FDA is simplified and unburdened, it will interfere with the industry's and in our country's ability to compete both at home and abroad.

I thank this committee for allowing me to speak.

[The prepared statement of Ali Gallagher follows:]

PREPARED STATEMENT OF ALI GALLAGHER, FOUNDER OF U.S. MEDICAL PRODUCTS, INC.

Mr. Chairman and Members of the Committee, my name is Ali Gallagher. I am the Founder and former Chief Executive Officer and Chairman of the Board of U.S. Medical Products, Inc., a company based in Austin, Texas. U.S. Medical is involved in the development of orthopedic, implantable hip and knee devices. This same week, four years ago, I started this company. And two months ago, after lengthy and costly delays at the FDA, I lost the company—to investors specializing in buying-up distressed companies. I want to share my recent experiences with this Committee and thank the members for holding these important hearings and for giving me the opportunity to submit testimony and appear before you. What I have to tell you is important because it effects our economy, and because it preserves or weakens the health of the public. But my words are not as important as the job you have as legislators because maintaining the status quo at FDA today is not just impossible, it is unconscionable.

I testified before the Subcommittee on Health and the Environment in July, 1994 in support of the Medical Device User Fee Act. My reason for doing so was to put a face on small business and tell this committee that efforts to improve the review process were critical to the survival of many small businesses. I detailed for you then my company's story—a company formed to provide comparable, quality medical products at a responsible price; a company that recognized an opportunity existed to bring highly-featured products to market at a cost substantially lower than the list prices of its competitors. We believed that we could be innovative, aggressively challenge the competition and—most importantly, gain FDA approval within the 90 day statutory time period set forth in the 1976 amendments regulating such device approval. After all, we were not reinventing the wheel, we were positioning ourselves to be substantially equivalent to the leading products on the market, improving them where possible, and lowering the price on items that were now costing hospitals on average an amount equal to one-half of their total DRG reimbursement payment.

In 1991 when we began, review determinations were made well within the ninety-day time frame from filing with the FDA to rendering of a decision. We factored this into our business plan and submitted our first Premarket Notification 510(k) application on a bipolar head (for use in conjunction with a hip system on patients with fractured hips), and received a favorable determination of "substantial equivalency" on the 106th day. About that same time we submitted our second 510(k) submission on a total hip system and after one year, were still awaiting product marketing approval from FDA. We went abroad to sell to survive. Indeed, but for product acceptance and sales in Europe, we would not have been able to continue as a going concern.

In June, 1993, still precluded from selling our main products in the U.S., I accepted our local Chamber of Commerce's Exporter of the Year Award and then proceeded to lay off one-half of our workers in an attempt to wait out the product review process. One month after our layoffs, 413 days after our submission, we received FDA approval on our hip system. We hired back key people and began again in earnest to grow our company.

It is important to point out that it was never an issue as to whether we would ultimately receive FDA approval. Our products were of the same materials as previously approved by the FDA, passed testing to the same cyclic fatigue properties, anti-lever out requirements, etc. as required by FDA and designed to be "substantially equivalent" to products being implanted prior to 1976 as per the statutory definition. We were not asking the FDA to allow us to market new technology, our improvements centered around improving the instrumentation used to implant the devices and various "locking" features necessary for intraoperative assembly of the device. But whether the technology was life saving, or cost containing, the companies were all stacked in the queque without priority and with no solid way to estimate the approval times or effectively plan for one's business needs accordingly.

The medical device industry is capital intensive and inventory costs for metal products run exceedingly high while inventory turnover has averaged about one turn per year.

Our search for capital was complicated by the delays at FDA—costing us far beyond what was contemplated in any rationale plan prior to the virtual work stoppage at the FDA. The unpredictability of the FDA, coupled with regulatory slowdowns and the uncertainty of health care reform caused a chilling effect on private investment money. Even venture capital money dropped 34% in 1993—almost $145 million. This reduction is massive when it is compared to the relatively minor drop in venture financing for the U.S. industry overall. According to a recently released report from the Health Industry Manufacturers Association, 51 public offerings generated $1.9 billion in investment for medical device companies in 1992. In 1993, that fell to $628 million and—as of June, 1994, U.S. Medical and 11 other companies went public—with the 12 public offerings generating only $222.5 million. By the time we went public in May, 1994, we were already delayed over a year for our knee approval. Still we were left with no meaningful way to gauge approval time or realistically plan for production. Without the knee—our flagship product, hip sales were negatively impacted because distributors and hospitals wanted companies with a broader range of products. In order to effectively compete in the hip market you also had to have a knee that your surgeon might need for his next patient... and our knee remained in a black hole at FDA despite tremendous demand for an affordable, high quality product that could have been available. Cost-containment considerations are immaterial to the federal review process even though about 72% of the surgeries being performed were payed for by the federal government through the medicare program. Despite lower cost and product equivalence to more costly devices, we were precluded from selling to more than half the world market—the U.S. is half the world market—by a federal agency unable to effectively or efficiently meet the task at hand—by a federal agency that had no way of immediately responding to small businesses put into a crisis situation by an agency unable to match regulatory requirements to the risks and benefits associated with devices.

Our knee approval finally came in the third quarter of 1994, almost 500 days after submission.

The expense of these delays in product review was well beyond even unanticipated market pressures. We were forced to again begin searching for dollars—with funding sources even more scarce. And so, after four years of building a company that was to bring savings to the hospitals it served, bringing its patented product improvements to the patients and surgeons using our products, after raising almost $7 million, half from small private investors and half through its public offering, after receiving over $2 million in revenues, gaining product approvals for both a total hip and knee line, obtaining international contracts with distributors in six countries and signing up U.S. distributors in eight states, I accepted the fact that for a $3 million dollar loan, the company that I and my team had built would essentially now be owned by an outside group of investors in the business of acquiring distressed companies. I gave them my proxy to enable them to acquire 80% of the company and thanked them for hopefully continuing what we had started... making high quality implants at an affordable price. But along the often difficult route a start-up company faces, after the many times I and the executives in this company made payroll out of our own pockets, I am certain of one thing, without the dream that we had a chance of succeeding, none of this would have been possible or undertaken.

Mr. Chairman, that dream of entrepreneurship... of innovation in the United States is seriously threatened, because the companies noted for breakthrough innovation—the small, start-up companies—are the ones who can least afford the increased cost associated with product delays. And seventy five percent of the 11,000 members of the health care technology industry are small businesses employing fewer than 50 workers. I cannot help but think that unless the regulatory thicket at FDA is simplified and unburdened it will interfere in our industry's—in our country's—ability, to compete, both at home and abroad.

I thank this committee for allowing me to speak and am available now or at any time in the future to respond to your questions.

Mr. BARTON. The committee thanks you for your testimony.

We would now like to hear from Dr. Arup Sen. Dr. Sen is a graduate with a Ph.D. in biochemistry from Princeton University. He is the founder and CEO of a company called HealthTech Development, Incorporated. This company engages in start-up ventures and corporate alliances to commercialize emerging medical and biomedical technologies.

In the past, he has managed the production, he has managed clinical trials and regulatory agency interactions for these biologically augmented medical devices, and also genetically engineered biological devices.

He has some concerns about the problems associated with obtaining venture capital for start-up medical companies because of the problem that Ms. Gallagher has just talked about to get FDA approval.

Dr. Sen.

STATEMENT OF ARUP SEN

Mr. SEN. Thank you, Mr. Chairman, and thank you the members of the subcommittee.

I have been engaged over the last 20 years initially trying to develop scientific technologies, primarily in the biotechnology area. Over the last 13 years have been suffering through the commercializing of many of these technologies. As you probably all agree, the main strength of our country is emerging technologies, although there has been a lot of support financially and politically for technologies that are supposedly going to be home-run and addressing billion dollar pharmaceutical markets.

The key to supporting the economy and supporting continuing technology development at our national research laboratories, and universities is going to be showing a clear predictable way of taking these technologies to the patient's bedside. Two years ago, I entered into actively trying to pursue medical device development that will be primarily, as we have heard this morning, device improvements. We are not talking about billion dollar products. We are trying to solve known medical problems with existing devices, one problem at a time.

We have identified a number of technologies over the last 2 years. I have invested my personal net worth as well as 2 years of my time into building commercially viable technology development programs. The second step in this, obviously, is receiving support, financial support. The major source venture capitalists, as Mr. Chairman has very correctly pointed out, has dried up because of many commitments to pie-in-the-sky programs.

The second level of support, which is corporate support, the regulatory approval process in this country for most products are so cumbersome and, more importantly, so unpredictable, that it actually is starting to support the existence and permanence of mediocre devices. It is a whole lot easier to support by giving a discount on an existing product than to spend in new technology which might improve the product because the latter has an uncertain return on investment.

As a result, we are, at our small start-up company, now faced with two options. One, closing it down and really not being able to pursue what we believe are extremely valuable, and that is capitalizing on the existing technology assets of this country.

The alternative is, which is something we are now in a position, unfortunately, to seriously consider, is for an investment and, just like you heard from Ms. Gallagher, the inevitable consequence of that is losing foreign product rights, losing control over the technology, and it is not unlikely that actually these technologies will now first be practiced outside of this country, and may never actually get back here and be commercialized.

I would urge that appropriate steps be taken to properly incentivize the Federal regulations as well as financial incentives that allow for these emerging technologies to move forward, allow people such as myself and the clinicians to decide what is reasonable in product improvement, and hopefully working closely with the FDA determine and develop a reliable more predictable path that allows the financial community to determine what kinds of investment they can make and what types of returns they might be able to expect as opposed to the current situation which is approval time variation, anywhere between 90 days to 800 days, which inevitably leads the financial community and corporate community to say, we simply don't want to take the chance.

Thank you.

[The prepared statement of Arup Sen follows:]

PREPARED STATEMENT OF ARUP SEN, PH.D., HEALTHTECH DEVELOPMENT, INC.

ISSUES RELATED TO THE MEDICAL DEVICE INDUSTRY: THE PERSPECTIVE OF A U.S. START-UP COMPANY

Our company, HealthTech Development, Inc., is pursuing medical applications of emerging technologies to create devices that are cost-effective and have improved functions. Our goal is to combine promising technologies, including those developed for non-medical purposes at the national research laboratories, in an effort to solve unmet clinical needs one step at a time. Significant technological discoveries, made at our universities and national laboratories over the past decade, have the potential to improve safety, durability, function and manufacturing cost of medical devices. A timely transfer of these technologies to the practice of medicine should benefit patients and enhance our global competitiveness.

For Implantable Devices, we are combining novel alloys with technologies for thin film coating and biological substances. Our goal is to achieve a progressive evolution of improved products in cardiovascular, orthopedic and dental fields. Coating of metallic screws, plates and artificial joints with the natural mineral found in bone will improve anchoring and tissue friendliness. New crack-resistant alloys will be used to replace and prevent failures from fractures of the current alloys in artificial joints and heart valves. New composites of a paste of natural mineral formed on a fine alloy or polymer mesh will make novel bone substitutes to avoid extra surgeries used in harvesting a patient's bone. Thin mineral film deposition technology will allow us to coat devices with biotechnology products to improve tissue friendliness and actually cause bone formation that reduce healing time. Novel void metal technology is being used create pores in mechanical heart valve rings so that the heart tissue grows in and coats the metal. These will avoid the risk and the expense of life-long anticoagulant treatment and make durable mechanical heart valves available to women of child-bearing age and to people with blood clotting disorders.

Our challenge is to logically combine relevant technologies, create product prototypes, evaluate their benefits quickly, and be able to follow a set of guidelines that (a) are not enormously complex and time consuming, and (b) enable us to reliably predict the tasks and timing to commercialization without having to consider the approval process as an uncertain, burdensome variable. Current concerns regarding the extent of regulation and the nonpredictability of the value of model tests towards the ultimate approvability and pricing of devices create three major problems:

- *Missed opportunities of promising technologies* (including many at the national laboratories already created for other purposes)—that would reduce the cost to manufacture or improve the quality of implantable and diagnostic devices;
- *Depriving patients of potential product improvements*—since the time and the expenses that need to be incurred by the companies in the development efforts may not provide a return on such investment; and
- *Compromised global competitiveness*—since it is difficult to justify investment in the development of an opportunity that is uncertain to enter the U.S. market and may have a reduced period of patent protection due to upcoming changes in the patent legislation.

The challenge for the U.S. medical industry in "maintaining" global leadership and benefiting patients at home at a pace comparable to that of technology emergence is to be able to (a) support an active conversion of emerging technologies into viable product candidates and (b) secure patent protection.

It is important to realize that a proactive identification and exploratory evaluation of new products from emerging technologies require a unique culture that also needs a unique support mechanism. Most technologies originate in the universities and national research laboratories without a specific commercial goal. Established companies who manufacture and market products focus on P/E ratios and market share to enhance the company's market capitalization. The incentive to provide sales support for an existing device is much higher and less risky than to pursue an improvement with an uncertain end result. Exploratory commercial R&D can be done most effectively through industry-academia collaborations in entrepreneurial companies whose goal is to search for new products and new markets for emerging technologies in different territories of the world. Given the long lead time for product approval, the technologies that are considered to be "home run" candidates are feasible to pursue in the current environment. The pursuit of "home run" candidates is still expensive and having to make such commitment drastically reduces the capital base to pursue other potentially valuable technologies. Thus many valuable emerging technologies that could benefit patients are not pursued due to the lack of an appropriate infrastructure with adequate support. Instead of capitalizing on promising technologies that are already available, there is a tendency to start over looking for the rare "home runs". I have personally found technologies at some of the national laboratories that have been developed for non-medical reasons and hold promise in medical applications. In fact, the novel alloys, thin film coating technologies and void light metal technologies are all in this category. Since these technologies are not perceived to be as valuable as a "*cancer gene that could diagnose and treat cancer and is discovered by a world-renowned medical scientist at a world-renowned institution*", they do not move to their logical next steps of application.

A mechanism needs to be developed that will support exploiting what is already there and create value out of existing assets.

Novel incentives are needed to encourage investments in "bridging the gap" between the emergence of technologies (which primarily occurs in universities and national research laboratories) and a proactive evaluation of their global commercial applicability.

The traditional sources of capital for medical product development are: established medical companies, and financial investors (eg. venture capitalists).

Consolidation in the medical industry has had a major negative impact on the corporate sources for capital, especially in the device industry where R&D for new product development has traditionally been limited relative to pharmaceutical and biotechnology companies. It is difficult to justify investments in early R&D in most devices since the profit margins for these products usually are lower than that for pharmaceutical and biotechnology products. This also is creating a new challenge in actively pursuing the application of biotechnology to improve medical devices.

Financial investors need a timely return on investment which is tied to product approval by the FDA. This requires that there is (i) an expedient approach to evaluate technologies in meaningful clinical situations and (ii) a reliable way to predict the "approvability (probability and timing)" of a product candidate based on animal or initial human evaluations.

In spite of much recent talks, there is a significant skepticism among corporations and financial investors in the medical device industry about reasonably assessing the probability and the timing of approval of a new product or product improvement, the duration of potential patent protection from the time of product approval, and the ability to demand higher prices for new products or product improvements that would justify early investment.

Entrepreneurial companies are limited in their ability to receive support for "bridging the gap" mentioned before and also face challenges in moving the product prototypes to commercial approval. There is an inertia that is fueled by regulatory approval uncertainties (time and requirements) and by the established companies with a market presence. Given the overwhelming cost and complexity of building the infrastructure of a fully integrated company, entrepreneurial companies depend on the support of established companies to pursue new products and product improvements. This poses an unusual challenge for a small company who has to convince an established company to invest in developing a product that may make a revenue-generating product obsolete, and yet the return on such an investment is uncertain. Such an environment stabilizes mediocre products since they are adequate. It also leads to a significant loss of value of emerging technologies since these become obsolete as the pace of technology emergence far exceeds the incentive to develop applications.

A plan needs to be implemented that addresses (a) the risk-to-benefit ratio requirement both to be able to initiate the evaluation of product candidates in a clinical setting and to receive approval to market, (b) the duration of post-approval patent protection (especially in the U.S.), and (c) the pricing of new or improved products in a practical manner so that there is a real incentive to invest capital in completing the development of product candidates.

On behalf of HealthTech Development, Inc., I would like to express my sincere gratitude for having the opportunity to present some issues that I believe are relevant to our strategy to capitalize on our leadership in medical technology innovation.

Mr. BARTON. Well, I thank you, doctor, for your testimony, and you also finished on time. That is unique almost.

We would now like to hear from Dr. Richard Ashman. Dr. Ashman is a Ph.D. in biomedical engineering from Tulane University. He is currently the President of Charter Research in Dallas, and head of Gabriel Medical Devices, Incorporated, a medical device manufacturer located in Lafayette, Louisiana.

His firms have completed development of proprietary core technologies concerning the identification of ducts, organs, blood vessels and other anatomic structures using infrared emission detection devices.

Dr. Ashman.

STATEMENT OF RICHARD B. ASHMAN

Mr. ASHMAN. Thank you, Mr. Chairman, and members of the subcommittee. I really appreciate the opportunity to speak today. It seems like a year ago an opportunity like this would have been unbelievable.

Going back to what was said in the earlier panel, my partners were very worried about me coming and testifying, and really didn't want me to refer to the companies by name. There is a general concern in the industry that there is some blacklisting going on or was going on, and I would suggest to the committee that you ask the FDA for their reference list, as it has been referred to, and really ask them to explain what it is and why those companies are on there.

Mr. BARTON. Would you suspend a second? While you say your partners were concerned, were you or your company contacted by anybody with the FDA and discouraged from attending?

Mr. ASHMAN. No.

Mr. BARTON. So this was a concern by your associates, and not necessarily a contact by——

Mr. ASHMAN. Yes. There was absolutely no contact, no. I didn't share their level of concern, I guess. I thought it was important to come and speak out, and do the right thing, I thought.

Anyway, estimates of the size of the industry have ranged up to $70 billion in annual sales. You know, America is still the leader in medical technology, but I guess the point has been made previously, what is the problem? My feeling is, it is in the slings and it is being loaded on the boat right now. I mean, medical technology and the industry is being offloaded into other countries as we speak. You have an opportunity to catch it before it is all gone.

Will America be the leader in 5 years? I don't know. Everybody I know is over in Europe all the time doing product development over there, people are setting up manufacturing over there. I will give you some examples of why they are doing that. There is a real spirit of cooperation between these various governments of some other countries and companies willing to develop the new technology on their soil, and America has to compete against that. We no longer have the complete market.

In the United States with my products, I generally have had little trouble with the FDA since my technique is to avoid the type of products that require complete PMA approval. The last device that was submitted was approved in 120 days, perfectly reasonable. But this was not a revolutionary product, and we expected a rapid approval.

The type of PMA study, on the other hand, takes an unknown number of years and millions of dollars, and I can't raise that kind of regulatory money. I must work on products that can be shown only to be substantial equivalent as sold as 510(k) devices. Any idea that I come across that requires a PMA, I have a choice, I can either choose not to do anything about it or try to consider developing it abroad, really a PMA is just not an alternative for what I intend to do.

You have to understand kind of what it is to develop a 510(k) device. You have to be within a very narrow window. First, the device must be new. If it isn't new, you can't get a patent. If you can't get a patent, you can't get any investors interested.

But also the device has to be old, it has to be shown predicate to 1976. So you have this narrow window between new and old. There are very few products that fall within that window. We looked at hundreds of products before we found one that we thought we could develop, get approval for, get patents for, raise money for and then sell. It is getting very, very difficult.

Apparently I am not the only one taking this approach. As an example, in the orthopedic segment of the industry, there have been thousands of PMA devices approved since 1976, but only around 30 PMA devices. Imagine 1,000 versus 30, and that is over a 20-year period. The paradox of the PMA 510(k) dichotomy is that it inhibits truly revolutionary products. The 510(k) concept to show equivalent was a good idea 20 years ago, there was nothing the matter with it.

But it now requires comparison to devices almost a quarter-century old. The technology of 1976 is getting a little stale. The FDA needs a mechanism to clear devices that is not as onerous as a PMA study.

When I first started in this business, the FDA showed more cooperation with business to do the right thing for patients. It has changed dramatically in the last few years. It is much more adversarial now. The industry is kept apart from the reviewers so it is impossible to explain parts of the filing that the reviewer may not understand.

By the way, you need to appreciate that many of the reviewers at the FDA, even though they are very nice people and try and do a good job, have little or no real life medical or clinical experience, they tend to be engineers or statisticians. It seems impossible for them to even make common sense decisions sometimes.

Another example of how current policy sends ideas and jobs overseas, suppose, for example, you have an idea to approve a device currently used only in Europe and you want to make that device here and sell it in Europe, export it only, not sell it in the United States at all. Do you realize that the FDA currently bars you from manufacturing that device here in the U.S. even if it is only to be exported. No other country in the world is so protective of the rest of the world yet so harsh on its own innovators.

How can you explain this to a machinist making implants in a small town in the country? I tried one time, and I was unsuccessful, he just couldn't fathom that at all.

Anyway, once you get clearance to market, the story isn't over. You have to refile for every little manufacturing or design change. The FDA says, sure, you can put a letter to file, but the risk of putting letters to file is like a time bomb ticking, you never know when they will come in on an inspection and say, well, that last change you made really puts you into the realm of having to refile. You have to take everything off the market. It is too risky.

The risks associated with refiling is significant also. You could be rejected and end up losing your existing business. No investors want to be a part of this kind of thing. The FDA's current mindset and its outdated treatment of medical devices serve as formidable opponents to new business development. The FDA most likely does keep businesses with outright fraudulent motives in check, but the other 99 percent of the industry pays and extremely high price, actually we all pay the price.

I don't think the FDA needs to be junked but rather just fixed. We need some modern laws. Will America be the leader in medical technology in 5 years? I hope so, but don't invite me back in the year 2000 for hearings on how we can entice the medical industry back, please.

[The prepared statement of Richard B. Ashman follows:]

PREPARED STATEMENT OF RICHARD B. ASHMAN, PH.D.

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I would like to thank you for the opportunity to speak about the difficulties of starting a medical device company in the present regulatory environment. Currently, I am president of Charter Research Inc. (Dallas, TX), a company formed to research medical technology and sell it to other manufacturers who then bring it to market. I am also involved in medical device development and manufacture with other companies, but they have asked me not to mention their names because they fear that it may somehow delay or adversely affect FDA action on pending clearance reviews. So, I will describe some of the types of products and devices on which I have worked instead.

Recently, I have been involved in the development of technologies and devices to identify various ducts, organs, and vessels during surgery. The first product in this line is a system that clearly identifies internal passages, such as ureters, during abdominal surgical procedures, thereby helping to limit the intrusiveness of the surgery and avoiding accidental injury. We have obtained 510(k) clearance from FDA to market our products in about 120 days.

The reason that FDA clearance was obtained with only a brief delay, in this instance and others in which I am involved, is that I deliberately choose to manufacture only those products that I suspect the FDA will clear. That is, I look for and develop ideas for devices that only meet the statutory requirement of section 510(k) of the Medical Devices Act, which requires FDA to clear for marketing those products found substantially equivalent to medical devices already on the market in 1976.

As an independent entrepreneur, I choose not to develop breakthrough products. The companies I work with cannot afford the cost, the time, and the uncertainties involved in pursuing that type of FDA marketing clearance. I have watched colleagues and investors throw millions of dollars and years of work into fruitless attempts to obtain FDA premarketing clearance for innovative, breakthrough technology only to end up broke or out of the innovative process. I'm too pragmatic—I need to work with devices from which I can earn a living. My statement today represents my own views and experience, and does not represent the views of Charter Research or the other companies with which I am involved.

The Medical Device Industry

The size and scope of the medical device industry in this country is not widely appreciated. To start, a medical device can be anything ranging from a diagnostic device, medical instrument, or patient implant to surgical sponges and CT or MR imaging machines that cost well over $1 million. Estimates of the size of the industry range up to $70.9 billion in annual sales worldwide (NIMA Report, "Healthcare Technology: an Investment in Public Health and Economic Growth for the 21st Century").

Although traditionally there are numerous roadblocks—financial, legal, and regulatory—when bringing new technology to the market, American medical device manufacturers have been the recognized world leaders in medical technology. America has enjoyed a history of high-tech innovation in products and market development supported by reliable outcome data and medical studies produced and conducted by clinicians and device manufacturers.

However, many device manufacturers like me have started to ask whether America will be the world leader in a few years. Many of my colleagues are spending increasing amounts of time in Europe and the pacific rim where there is a spirit of cooperation between the foreign governments and companies willing to develop the new technology on their soil; unlike the adversarial relationship between device manufacturers in this country and FDA. Further, other countries place more trust in the highly trained health professionals or medical societies who best understand the technology, rather than trusting government bureaucracies when it comes to accepting new medical technology. So, although I do not know in what state the medical device industry will be in the near future, I hope that you do not invite me back in the year 2000 for hearings on how we can entice the industry back from Europe and pacific rim.

Starting a Medical Device Company

Developing medical devices is what I was.trained to do, with a bachelor's and master's degrees in mechanical engineering and a Ph.D. in biomedical engineering. I have worked in this field for over fifteen years, and I do not know any other profession. My experience has taught me that to be successful in a medical device startup venture, I need infinite patience, determination, and the ability to persevere for a very long time without reward. The frustrations and barriers involved in overcoming the regulatory hurdles are significant, and those who cannot go the distance are shut out of this industry even though they may have excellent ideas.

The 510(k) Review Process

To start the companies with which I am now a principle, I and my partners needed very measured, carefully crafted ideas—not just any idea that might improve the delivery of medical care. This is because of the paradoxical demands of the FDA regulatory process. Under the most frequently used FDA review process for medical devices, usually referred to as 510(k), the idea for the new device must be OLD; the 510(k) application must show that the new device is substantially equivalent to a device that can be traced back before 1976. Conversely, an idea for a 510(k) medical device must be NEW; otherwise you cannot obtain a patent. Without a patent, no investors will be interested. So I have learned that to survive under the present regulatory regime, my new products must fit within the narrow window of the old-new dichotomy mandated by the 510(k) process.

The most fundamental problem with the 510(k) process, a problem Congress hopefully will resolve, is that it inhibits truly revolutionary products. Thus, it is often said that most devices are evolutionary, not revolutionary. Nonetheless, although the 510(k) process has its shortcomings, it is the only viable option for most products developed in the U.S. today.

The alternative to the 510(k) process is the full premarket clearance review, which because of its costs in dollars and time often is no real alternative at all—certainly not to a small, start-up company. For example, notwithstanding the difficulties of obtaining 510(k) review, there have been thousands of 510(k) orthopedic devices approved since 1976, but only about thirty PMA orthopedic devices have been approved during that same time period. These statistics, which the Committee could ask FDA to verify and update, suggest that many companies have all but given up on the development of breakthrough products in the U.S.

The Premarket Approval Process

Any truly new or revolutionary device, which has no predicate 1976 device on the market, must undergo PMA review requiring a costly patient study and follow-up. A PMA study takes an unpredictable number of years and lots of money. Yet many breakthrough devices and treatments are intuitive and obvious to health care providers—they are the natural and logical result of a process, treatment, or increase in knowledge. In some cases breakthrough devices are very simple. A costly patient study may not be necessary. It should not cost a fortune or take a decade to make these types of innovations available to patients who need them. But because there is no predicate device on the market, the law requires compliance with the full PMA process.

Some very smart people with innovative products are going broke trying to get their products approved through a PMA. The cost of an average PMA study is currently well above $1 million. For that reason many American innovations are presently being developed outside of the U.S. Also consider that while the PMA study may take several years, the seventeen year time limit for the underlying patents is running out. In addition, while the PMA study is underway the device cannot be modified, even if a competitor were to introduce a more advance version of the device that makes your PMA device obsolete. Consequently, delays in the regulatory process undermine the value of the investment in the new device, drain capital, and threaten the very survival of the small company.

Based on my experience, I am unable to justify taking my start-up companies down the PMA route. Although I personally know of several very innovative products, they would require PMA studies since no predicate device exists. I was approached only last week by an obstetrician who had an idea for a device that would help pregnant women in whom labor had to be induced. The device would monitor fetal contractions in women in labor in order to adjust automatically the dosage of the labor-inducing drug that was being used. Theoretically, this could provide more rapid and accurate dosage, and it would free the physician from a purely monitoring task to provide other medical services.

I could not take a serious interest in the device because it would be just about impossible to obtain FDA clearance since there is no predicate device on the market. It is unlikely that anyone else will bring this idea, or similar breakthrough ideas, to the market in the U.S. because the developers would not be capable of recouping the costs, for themselves or investors, of the PMA studies and obtaining FDA marketing clearance. Neither I nor my colleagues can quantify the costs to our society of some very inventive ideas for new medical devices that were not pursued or that were abandoned because the PMA process was too great of an obstacle for the little guy.

America needs a mechanism to obtain FDA marketing clearance for new devices that is less onerous than the PMA process, yet which does not require establishing a pre-1976 predicate device as a comparison. The 510(k) concept was a good idea twenty years ago but it now requires a comparison to devices twenty years old. The technology of 1976 is stale and with every day that passes, it supports fewer new products that can significantly advance public health.

The Regulatory Process Drives Innovation Abroad

Suppose you have an idea to improve a device currently used throughout Europe but not cleared for marketing here in the U.S. Current FDA regulations bar you from manufacturing the uncleared device here in the U.S. and exporting it, even if it is to be sold only in Europe. In order to export a device that was manufactured in the U.S. for sale abroad, you need to obtain precisely the same FDA marketing clearance that must be obtained to market the device in this country.

If it is a breakthrough product, the delays involved in obtaining FDA clearance would allow competitors abroad to take over the market. Under these regulations, the only viable option would be to manufacture the improvement abroad, diverting jobs, revenue, and improved medical care away from the U.S. In fact, I am pursuing several ideas for manufacturing new breakthrough devices in Europe, where I know I can bring the products to market and attract investors. I cannot discuss these nascent devices before the Committee because they do have significant potential for development abroad. No other country is so protective of the rest of the world, yet so harsh on its own innovators.

Once you get a new medical device reviewed and on the market, you must refile with the FDA for permission for every change in the manufacturing process or design modification. Imagine how slow innovation would be if every time you improved a computer you had to file for permission with some government agency. Imagine the cost. Although improving a product is in a company's best interests in a free market, I know of instances where companies chose not to improve devices due to the risks associated with refiling with the FDA.

These risks are very real. There is the possibility that the FDA will reject the 510(k) application for the improvement even though the product may have been on the market for years. After the 510(k) is denied, the company must sort out what is and is not cleared by the FDA, keeping the uncleared product off the market and possibly losing the market. There are even greater obstacles to improving a device that had been cleared via the PMA process. The FDA could require a new patient follow-up study and the company might end up being able to provide the new, improved version to only a few doctors, while the old out-dated products are still widely available. When the export restrictions, incentives for moving abroad, and risks inherent in modifying existing devices are all considered together, the picture that emerges is of an industry that is being strangled by the current regulatory environment.

SUMMARY

Most medical devices available to U.S. doctors and patients have been cleared by the FDA using the 510(k) approach, and therefore, most devices are evolutionary. Most 510(k) applications seek routine minor improvements of existing devices. Filing PMA's for breakthrough products is extremely expensive and often too risky for small innovators. The FDA serves as a formidable opponent to small business development.

The FDA most likely does keep people with outright fraudulent motives in check, but the other 99.90% of the industry pays an extremely high price. Actually, the patients and the U.S. Government (through Medicare and Medicaid) pay the price. Congress should change the mind-set of the FDA to establish a spirit of cooperation with American innovators to work together to do the right thing for patients. Let's not give the American device industry away. After all, every U.S. citizen should have a chance to receive the most advanced American medical treatment possible.

Mr. BARTON. I thank you for those comments. I don't intend to be holding this same hearing in the year 2000.

The Chair would now recognize himself for a series of questions.

Ms. Gallagher, you have painted a fairly bleak picture of the approval process at FDA. Now the devices that you submitted, from what I understand, and I am not a medical device expert, but these were not devices that should have required a PMA approval; is that correct?

Ms. GALLAGHER. That is correct.

Mr. BARTON. So you were in either Class I or Class II?

Ms. GALLAGHER. Class II 510(k) process, the 90-day statutory time period premarket notification. Before 1990, the companies that were marketing devices under the premarket notification simply had to give the FDA a 90-day lead time that they were planning to go to market, and if in 90 days they hadn't heard from the FDA, they could simply go to market. A few of them, and I am not sure I know of any that went, they still waited, but in 1990 the laws changed and you had to get affirmation from the FDA to go to market.

Mr. BARTON. Now the FDA appeared before this committee last year, last Congress, and said that if we would just give them more money and more people, that they would bring this approval process into line. In fact, they presented a timetable, Class I, Class II, Class III, that if we would just give them some of these user fees, they would meet these targets. It was their numbers, their targets, it was not generated by the Congress.

Yet, in your case, the devices that you were asking to be approved should be approved under the FDA guidelines in 90 days, and while they were approved in both cases that you mentioned, it took over a year, almost a year. What do you attribute the delay to; do you attribute it to a backlog at the FDA; do you attribute it to incompetence that they just flat didn't understand what it was; do you attribute it to indifference that they just for some reason had an aversion to your company and wanted to string you along; what caused the problem of the delay?

Ms. GALLAGHER. I don't think I am that persecuted. Basically, at those hearings, Dr. Kessler also mentioned that there were 4,000 devices in FDA looking for approval for 510(k) process. On many occasions informally, talking with some FDA reviewers, we were told that at there were only two people in the orthopedic side reviewing cases. That posed a great deal of concern to me knowing that I was in there and I was essentially there with a me-too product.

I don't know the answer, not enough reviewers, the backlog, the numbers, were overwhelming. But let me add this, I said I had a knee and a hip. I actually had six products. I did a hip and then I did the same hip in titanium as opposed to my approved one in cobalt chrome. I tested it pursuant to the guidelines as to titanium. I then sprayed it with hydroxy apatite like a lot of people out there going to same vendors got their products sprayed or the hydroxy apatite applied, the same identical instruments were used. I changed nothing in the hip design, and still those other hip products took over 300 days each.

Mr. BARTON. Now would one possible solution to the problem that your company encountered be some sort of a peer review panel by the National Institute of Health or some of the professional boards that would use your products; would that have solved the problem in your case if they had farmed it out, so to speak, if FDA only had two people?

Ms. GALLAGHER. If they had farmed it out and I had review, absolutely. I mean the delay is what cost us, and not so much even the delay as the unpredictability. I would have situations where we are out looking for money, and I couldn't tell investors when I could expect FDA approval, or if I made an educated guess going by the averages that Dr. Kessler and others were saying were the review time averages, we were off, we were off quite a bit.

Mr. BARTON. Do you have any idea, during this time period, how much of that was actually spent reviewing your devices? I mean, once they got to it, do you think it took them a couple of days?

Ms. GALLAGHER. It took them a week.

Mr. BARTON. A week, 1 week.

Ms. GALLAGHER. Yes.

Mr. BARTON. Okay.

Ms. GALLAGHER. Which is why I was sitting here saying, let me pay the $3,200 to have somebody in 1 week get me my product approval.

Mr. BARTON. One possible solution, it is probably not practical, but we could dock their pay. We could say, if you don't have it done by a certain time, it is going to cost you X number of dollars a week out of your own paycheck, or Dr. Kessler's expense account, or something, and they might decide to reallocate resources.

Dr. Ashman, you indicated in your oral testimony that there needs to be another review process. Your exact words were "a mechanism not as onerous as a PMA." Do you have any suggestions about what that mechanism might be?

Mr. ASHMAN. Well, the time tested method to accept whether or not medical treatment is efficacious is through a prospective medical type study where you take the device and apply it to the patients as it is suggested to do and then look at the results. That is over a prospective period.

The FDA is very reticent to look at retrospective studies, and I am not a statistician, and there are a lot of epidemiologic people who can talk about the pros and cons of these things, but my experience with the FDA is not one that they want to take a lot of time. I think they just really can't make those simple decisions because they don't have the background.

Mr. BARTON. Well, give me an example of a simple decision that they couldn't make or had trouble making.

Mr. ASHMAN. Well, I know of a particular device that was used to anchor sutures in bone, and from what I understood through a conversation from one of the reviewers at the FDA is that their initial approach was to look at studies for each and every individual bone in the body for this thing rather than just does it work or doesn't it kind of in an general or global way.

There could be, for example, type approval. For example, many orthopedic devices are made out of one particular alloy of stainless steel. Why not make it such that if you use this particular alloy there should be no question of biocompatibility as to you. I mean, it is ridiculous to ask these same questions of biocompatibility to every individual person that comes with the same exact alloy. By the way, the alloy is only available from two vendors worldwide, so it is pretty much the same stuff. As long as you are certifying through your GMPs that it is the proper alloy, and have your documentation, that would be a no brainer.

There is no type approval of power supplies. You can't just take a power supply off the shelf that would be necessarily approveable because it carries some special UL designation. You have to go through the entire process each time.

Mr. BARTON. My time has expired.

The Chair now recognizes Congressman Wyden.

Mr. WYDEN. Thank you, Mr. Chairman. I think this has been an excellent panel, Mr. Chairman. All of you have provided some concrete real world cases.

I am of the view that the Food and Drug Administration needs to be more entrepreneur friendly, and I think it can be done consistent with their public health mission to focus on the safety and efficacy of these products.

I would like to ask you about a couple of ideas that I am looking at. I am working on my own package of FDA reforms, and I haven't fixed on any ideas yet formally for unveiling, but I want to ask you about two that we have discussed with some entrepreneurs.

A number of entrepreneurs that we have met with indicated that they would be very interested in seeing the rules relaxed and specifically for the lower risk devices at the front end.

The rules would be relaxed at the front-end so that companies could get the product out, and begin to start generating revenue, which is so critical for the small entrepreneurs. In return there would be an effort to increase postmarket surveillance so that we could go out and actually see how it is working. This strikes me as the kind of idea that Mr. Barton and I could team up on, that could be bipartisan, that could really make a difference for the risk takers and these small firms, and be consistent with the kind of mission that the FDA has.

Why don't we start at that end, and I thought I got some nods, which sounded encouraging.

Mr. ASHMAN. That may work very well for the low-risk devices. Again, you know, we are talking about devices here, we are not talking about drugs. People have brought up Thalidomide and other things. These are not drugs. A lot of them are really no brainers.

For example, if I came up with something like dental floss today, if it didn't exist before 1976, I would have to do a PMA study. Yet, do you——

Mr. BARTON. Would you yield? What is magic about 1976, you said that in your opening statement, and I didn't understand that?

Ms. GALLAGHER. The 1976 amendments, it is the cutoff point. If you had a device on the market prior to 1976, then it just stayed on the market. It you came after 1976, under the 510(k) process, you had to show that you ere substantially equivalent to a pre-1976 device. Then if you went further, you had——

Mr. BARTON. So that is a statutory problem. I mean, that is a law that we need to look into.

Ms. GALLAGHER. It is just a line in the sand.

Mr. ASHMAN. Right.

Mr. BARTON. We have frozen technology in 1976.

Ms. GALLAGHER. You got it.

Mr. ASHMAN. Yes, and it is getting a little dated, that's all.

Mr. BARTON. It was a good year.

Mr. ASHMAN. Yes, May 1976. But such a concept might work very well for these low-risk devices.

Mr. WYDEN. Our other witnesses, doctor?

Mr. SEN. Yes. I think that is probably an excellent idea. In fact, in some respects, in the biologics especially, there are some easier ways of getting prototype products, if you will, into clinical trial and getting them evaluated in patients. The problem still remains, and this is where I think a more systematic thought process needs to go in, is even after demonstrating in a live clinical scenario that a device or a product is reasonably working reasonably safe, that there is any timely assurance of predictable approval.

Somehow, fixing the technology base at this magical May 1976 timeline creates a problem for new technologies which need to be looked at with a newer view and what it really should take to create a safe device. The general concern that all industry people and clinicians are not to be trusted, and they will deliberately try to hurt people is a rather strange attitude. It is a self-policing system, and very few people, as you probably heard this morning, very few doctors will put in a bad device, and very few industry will survive if they market a bad device.

Mr. WYDEN. Ms. Gallagher, don't feel compelled to answer because maybe I can ask another question, but we would be happy to have your views.

Ms. GALLAGHER. Just a short addition, I like the concept very much, and I would only add to it that for the first year or whatever time after there has been some debate on it, there needs to be a period of relaxation for what I call continuous manufacturing improvements once a device is out there and it is in the hands of many, we need to be able to get a quick read and quick change.

Mr. WYDEN. That is a thoughtful suggestion as well, and we may want to be on the phone and ask you some more as we prepare this package.

Let me ask you about one other idea that we have been looking at, if I can get this one in. When you are talking about a simple design change at the Food and Drug Administration, I think it is outrageous that people should have to go through bureaucratic water torture for those kinds of changes.

What would you think about the idea of just setting a deadline, say 30 days, or 60 days, or something like that, and say, if there is no answer in terms of a request for a simple design change within that time, then you may just go ahead and make the design changes as if there was a formal ruling.

Mr. ASHMAN. Gee, back to the future, that is the way it used to be.

Mr. WYDEN. All right. That is an endorsement, I gather.

Mr. SEN. Let me make one quick comment to that, though, and that is, the investigational device exemption process is supposed to be done that way. The problem is, on day 29, you get a series of questions, submit the answer, and the clock starts ticking again.

Mr. WYDEN. Ms. Gallagher.

Ms. GALLAGHER. I am in agreement.

Mr. WYDEN. The only other area I wanted to ask you all about, if I can get this one in, Dr. Ashman, you discussed impediments in developing new products that included the investor community. How much of the reluctance on the part of the investor community in your view can really be put at the FDA's doorstep?

Mr. ASHMAN. A percentage would be hard to say. But, for example, in many businesses plans that you look at, everything is laid out pretty clearly until you get to the regulatory side, and then it gets real iffy.

Part of the problem with the FDA right now is the uncertainties associated with it. They seem to make such arbitrary decisions sometimes. Sometimes a review takes a short period of time for a difficult device. Sometimes it takes an extraordinary long time for a very simple device. It is the arbitrariness that I think most affects the investment community. If they knew how long it would take, they could put a value to it or a price to it. That arbitrary, it is just hard to get your arms around.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. BURR [presiding]. You are more than welcome.

We have shifted seats just a little bit so that our chairman can make the next vote and then make his plane, and I am going to take my time here at the chairman's seat, if I could.

Ms. Gallagher, let me start with you, if I could. Your product or your bag of products that your company had, were those, to some degree, copies of existing devices that were on the market?

Ms. GALLAGHER. I would say yes, but my marketing guys probably wouldn't agree, but essentially yes.

Mr. BURR. Should there be a difference in the approval process for that initial product for the ones that come after it? I mean, there is a significant cost for that first person through. Can you help us understand, should there be a difference?

Ms. GALLAGHER. Well, there should be, and there really is a difference, and that is the 510(k) process. By definition, any product that comes in under 510(k) has to show that they are substantially equivalent to a product already out on the market, whether it is a hip, or a knee, or a bipolar, that is what you are showing.

Now my hip, for example, my instruments were a little different, but the FDA is not regulating the instruments, and what we claimed is basically that we had all the features of the high-dollar items out there, but we had the same neck lengths, the same angles.

Mr. BURR. Let me ask this about the approval process on any one of your products, from the time that you submitted that product for approval, how significantly did that product change when the approval came?

Ms. GALLAGHER. No major change, no major change out there.

Mr. BURR. So very little input back from FDA as far as specific changes?

Ms. GALLAGHER. Yes, that is true for what I was doing, but it may not be at all for other people. In my business, if you had a hip, what did you have a cobalt chrome one, a titanium one, one with hydroxy apatite, and we basically moved to have all of them. You needed the complete selection to go out and sell to a physician. If he found himself in surgery needing a press fit, you needed to have it. If he needed a cemented version, you needed to have that. These were all separate submissions.

Mr. BURR. During the approval process, how much correspondence did you have with FDA?

Ms. GALLAGHER. In the beginning, I would say 1992-93 up to 1994, really very little, none on some products, and we might have been asked a question or two on one product. In 1994, they implemented the means of checking to see where you were in the queue, so then every month you would fax in a request that you wanted to know where you were in the queue, and within 3 days you would get your answer.

But the answers were meaningless. One time I was 200, and the next month I was 100, and then on a different product I was zero or number 1, and then the following month I was number 1, and the following month I was number 1.

Mr. BURR. So not something that you could confidently count on for purposes of business planning?

Ms. GALLAGHER. No, and that is key because you have a manufacturing lead time, and most of my money went into inventory. So there were a few times when I made the mistake, I said, here is when, here is the outside at FDA, order that stuff, and I pushed the manufacturing button, and vendors all over, little companies with 10, 20 employees making some of the component parts for me and for the large companies, and then it was all coming in and I had no approval, no cash flow coming in, and I had to pay for these. I left a lot of vendors waiting and wondering how they were going to make payroll.

Mr. BURR. If an entrepreneur came to you today and said, help me write a business plan for a start-up medical device manufacturing business, what would you say to them?

Ms. GALLAGHER. You know, I wouldn't do this again, and let me tell you why. Sitting there, even getting my products approved, you would think, well, okay, she has got them. Well, I really took this very seriously. You go out there and you sell these things, and then you get complaints and every single company gets a complaint and has a complaint file. It is the first thing FDA asks for when they visit your facility, where is your complaint file. If you don't have one, you are lying. So we all have them.

When you get the complaints back, you really have to decide if you are seeing something that needs a product improvement, and you don't have the ability to do anything other than wait a while, call it a letter to file, and not submit for a new application on a 510(k) change.

Mr. BURR. And adjust your business plan.

Ms. GALLAGHER. I mean, I don't want to sit anymore with that kind of responsibility on my shoulders.

Mr. BURR. Did you ever estimate how much of the cost of the products that you manufactured were directly derived from regulation?

Ms. GALLAGHER. I am sure some bean counter there has that number, but, you know, R&D costs, and we had our regulatory in that, sometimes ran as high as 75 percent of our costs.

Mr. BURR. And I know your marketing people wouldn't like that, but that is for a copy product?

Ms. GALLAGHER. Yes, it is for a copy.

Mr. BURR. Let me just go over to Dr. Ashman for a second. You stated that the FDA bars the manufacturing of medical devices for export. You turned to export for your survival. Can you two help me work through where the difference is between which products can and cannot or if all can what do we have to do to go through it?

Mr. ASHMAN. Well, I don't know about in her case, but you can export unfinished products. For example, you can export an assembly to be assembled elsewhere. In fact, many people do that. They will make subassemblies in the United States, ship them to Europe and then have them assembled into the final product, and many people are doing that now as to kind of technically avoid the fact that they would be violating the FDA's policy of exporting an unapproved product.

I don't know what mechanism you used.

Ms. GALLAGHER. Well, we had limited experience. We sold to Italy, and we readily received export certification from the FDA to do that. Italy had really very little in the way of requirements, but there were other countries that did require that we publish studies, and we were really unable to meet their requirements because at home, where we had our doctors and planning physicians, we were precluded from implanting. No studies, I can't go out and apply in the country that requires that I have published my finding.

Mr. BURR. Okay.

I thank you very much. The Chair recognizes Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman. I just wanted to ask unanimous consent to put into the record an article from the Washington Post, February 22, 1995, involving the sensor pad. As our colleagues know, this was much discussed again today, and I think we may have ended up perhaps inadvertently putting some more inaccurate weight behind what really happened in this case, and I would just ask unanimous consent that this be put into the record.

Mr. BURR. Without objection, that will be entered into the record.

[The article referred to follows:]

BREAST EXAM PAD IS USED AS WEAPON AGAINST FDA

CLAIMS OF FAST CANADIAN APPROVAL FAIL TRUTH TEST

[Washington Post, February 22, 1995]

By John Schwartz

The Sensor Pad, a little plastic sandwich designed to make it easier for women to examine their breasts, has been a powerful weapon in the hands of lobbyists who would like to rein in the Food and Drug Administration. They claim the device, still not licensed for marketing in this country, was approved by Canadian authorities in less than 60 days.

There's only one problem: It's never been approved in Canada either. "No device is approved in Canada," said Mary Jane Bell, the acting head of the part of Canada's Medical Services Bureau that oversees such products. "The U.S. FDA approves devices. We do not." Instead, Canada allows companies to market new medical devices, asking only that the government be notified.

In fact, the Sensor Pad is actually banned in Canada until the company provides the same kind of information on effectiveness demanded by the FDA. Bell said. After the company notified the Canadian government that it was entering the market, officials asked the manufacturer, Inventive Products of Decatur, III, to show that the pad actually aided in the detection of lumps. The company did not comply, and the Canadian government sent a letter on July 27, 1994, prohibiting the pad's sale there, Bell said.

FDA's critics have repeated the claims of speedy approval nevertheless. In April 1994, the Wall Street Journal reported that the device was approved in Canada "in 30 days." In an August report on ABC's "20/20," reporter John Stossel said, "In Canada they approved this in less than 60 days." A similar claim was made by the Washington Legal Foundation in an advertisement earlier this year.

Citizens for a Sound Economy took it one step further, using incorrect information about the Sensor Pad in a survey of attitudes toward the FDA. Months after the company received news of the Canadian ban, the conservative group hired Republican pollster Frank Luntz to conduct the survey. One question stated, "The Sensor Pad" is a device designed to help women detect breast cancer. It was approved in Canada within 60 days. The FDA estimates that it will take 9 years of testing for approval. Do you favor or oppose the fact that it will take 9 years of testing for approval?" Predictably, 76.9 percent were opposed, while 17.6 said they favored the lengthy approval process.

With the survey audience prepped by the Sensor Pad question, Luntz's pollsters asked, "From what you have learned, do you have a very favorable, somewhat favorable, somewhat unfavorable or very unfavorable opinion of the FDA?" Of those polled, 29.8 percent had a somewhat or very unfavorable opinion of the agency; 61.4 percent maintained a favorable view.

Jeffrey Pierce, a regulatory analyst for Citizens for a Sound Economy, said he had not heard that Canada had banned the Sensor Pad. "To be perfectly honest with you, I have not studied the Canadian system in depth," he said.

"The problem still remains with the FDA," Pierce added, because the agency is too restrictive in its approval process.

FDA officials said that no one at the agency ever told the company that approval would take nine years. After failing to get FDA approval for its initial application in 1985, Sensor Pad inventor Earl Wright tried to go around the agency by selling the device directly to hospitals, which landed the company in a losing court battle with the FDA. "I never dreamed in my worst nightmare of what we've been through the last ten years," said Wright, 65, who came to Washington in January with his son, the president of the company, to testify before a House subcommittee. "I will probably never develop another product."

Cynthia Pearson, program director for the National Women's Health Network, said that inventor Wright brought much of his bureaucratic nightmare on himself. "They could have done it ten times over in the time they've been fighting the FDA," said Pearson, who questioned the device's effectiveness before an FDA advisory panel last year.

"I think the company has shown over a period of years that they're unwilling to do the necessary tests.... It's reasonable for the FDA to ask that those kind of studies be done," Pearson said.

Wright maintains the Sensor Pad has distinct advantages over self-examination in the shower: "Some women don't like to touch their breast, so this puts something between the breast and hand without destroying the sense of touch." Now, his company is trying to get FDA approval once again, and Wright said that things are looking up. "I think they're moving. I think they want to cooperate." He said company officials are meeting with the FDA next week to discuss tests that could pass muster.

Mr. BURR. Let me take this opportunity for Chairman Barton and for this complete subcommittee to thank you for your testimony and the testimony of those before you, to tell you that we are genuinely interested, both sides of the aisle up here, to ensure that we have a process at FDA that protects consumers, that is understandable by those that are manufacturers in medical devices and, first and foremost, attempts to save lives in the cases where that is certainly the key element. I thank you for coming in today.

This hearing is now adjourned.

[Whereupon, at 1:27 p.m., the subcommittee adjourned pursuant to call of the Chair.]

[Additional material submitted for the record follows.]

OPENING STATEMENT OF HON. THOMAS J. BLILEY, JR., CHAIRMAN, COMMITTEE ON COMMERCE

Mr. Chairman, first let me congratulate you on holding today's hearing on a topic of profound importance to the health of the American people. Medical devices, like drugs, not only save lives, they also save dollars—federal and state taxpayer dollars that are getting more scarce every day, third party payer dollars that ultimately come from consumers, and out of pocket expenses and lost wages that are directly paid by individuals.

Breakthroughs in medical technology should mean lives saved, pain and suffering avoided, higher productivity achieved and more jobs for our economy gained. Sadly, some of these benefits have already been lost and, if we continue on our current path, much more will be lost in the future.

According to the American Electronics Association, 40 percent of medical device manufacturers have laid off workers, 29 percent have increased overseas investment and 22 percent have moved U.S. jobs overseas. The latter are the fortunate companies. Many of the medical device firms are startups, depending on venture capital that has all but soured on firms that depend on FDA approval to market their products.

The average review time for life-saving devices called PMAs, the most potentially important products, is over 400 days despite a specific statutory requirement of review within 180 days. No European or Canadian medical device firm has to wait anything like this long for approval from its regulatory authorities. Can anyone seriously doubt that the Swedes or Canadians care less about protecting their citizens from unsafe or ineffective medical devices? The delays in the U.S. are not a function of a greater concern for safety and health. Indeed, we are the victims of what can be called the bureaucratic or regulatory imperative.

Congress passes a basic law, in this case the Food Drug and Cosmetic Act (FDCA) that requires that drugs and medical devices be both safe and effective. Because we cannot review each and every product brought to the market, authority to determine what is safe and effective is delegated to a regulatory agency, in this case the Federal Food and Drug Administration (FDA). The FDA then makes rules and policies and decisions over time that make less and less sense in individual cases but that the bureaucrats believe are either necessary to assure consistency with the past or to cover "worse case scenarios" that might arise in the future.

Bureaucrats quickly learn that high profile errors of commission can devastate a career but that equally catastrophic errors of omission can go unnoticed. Finally, in a few cases, they learn that the black box of confidentiality can protect them from not only excessive caution but personal weakness and greed. This leads to scandals that this subcommittee has rooted out several times in the history of our oversight, most recently in the generic drug approval process.

I am not suggesting that bribes are the driving force behind the current problems in the FDA medical device approval process. I am suggesting that the bureaucratic culture of caution and delay has produced a situation where avoidable loss of life and health occurs every day in this great country of ours not because of charlatans peddling dangerous medical devices but because of bureaucrats that have not done their jobs as Congress intended and that taxpayers pay them to do.

As the ranking Republican Member on this subcommittee, I have supported investigations into FDA incompetence and mismanagement of generic drugs, medical devices, imported seafood and other foods, drugs, and many related topics. I believed that those inquiries were conducted in a fair, fact driven manner. We cooperated with those investigations and the former Chairman, Mr. Dingell, set the standard for how productive, even-handed oversight should be conducted. However, with all due respect to my friend from Michigan, the adding of resources to the FDA has not solved the problem. The bureaucratic imperative remains.

Unfortunately, I expect that today's hearing will just be the first in a series of lessons in the damage that the culture of caution that has become a prescription for paralysis at the FDA has done to our citizens. If my suspicions are correct, I am prepared to subject both the FDCA and the FDA to comprehensive overhaul in this Congress.

RESPONSES TO QUESTIONS FROM HON. JIM GREENWOOD BY RICHARD B. ASHMAN

Question: A company in my area is the world's leading producer of *in vitro* diagnostic tests—or IVD's—used in the management of cancer patients. Here in the United States, *in vitro* diagnostic tests are subjected to the same extensive testing and FDA scrutiny as medical devices like heart valves or other devices implanted into the body or used for life sustaining purposes. Unfortunately, after investing nearly 10 years and 20 million dollars seeking FDA approval for these products, only one has ever been approved for use in the United States and the vast majority of Centocor's commercial activity is located abroad where these products have been used successfully for many years.

Aren't we having the FDA regulate these diagnostic tests too much? They don't have the potential to be intrinsically unsafe because they are never used on or in the human body. Shouldn't FDA's evaluation of new IVDs recognize that they are in a lower risk category than heart valves, and subject them to less extensive evaluations than products used on or in the human body?

Response: I believe the FDA overregulates all devices too much, not just diagnostic tests. The point that needs to be made in whatever new law or mandate that emerges for these hearings is that devices and diagnosis tests are not drugs and are difficult to regulate like drugs.

Question: By Congress's mandate, the FDA is supposed to decide on 510(k) notifications within 90 days. Premarket approval or "PMA" applications are supposed to be resolved within 180 days. But the FDA ignores these time limits and many applications are subject to much more lengthy reviews sometimes taking several years.

Doesn't it make sense to reverse the burden and permit a manufacturer to market a new device to medical professionals after the FDA has had the 510(k) notification for 90 days or the PMA application for 180 days unless the FDA had concluded that it was unsafe or not effective within that time? Wouldn't that give those who develop medical technology assurance that if the FDA decision was delayed beyond the Congressionally mandated time periods, the delay would not bar them from the market? The FDA would continue to have the jurisdiction to approve or disapprove the device as well as to exercise the post-market enforcement powers that it presently has, but the device would be available on the market in the meantime, with appropriate disclosures to medical professionals that FDA approval was still pending.

Response: A few years ago the FDA was held to a strict timetable on deciding 510k applications. I know of only one instance where a company decided to call a device cleared because the FDA was late. Many people believe that such a decision caused this particular company more trouble than it was worth.

In a practical sense, such a strict timetable only sets up a company for future problems. For example, is the device really cleared or not? Suppose a patient claims harm from the device? Would the company be able to defend its "clearance" in court? What would happen with future modifications of the device?

I know most companies would like to get back to a strict timetable. The FDA seemed much more responsive when held to a timetable. However, I would not expect many companies would risk selling a device that was cleared by elapsed time.

Question: Congress mandated that the FDA find that a new medical device is "safe and effective" before it is marketed here. There is no clear definition, however, of what "safe" and "effective" mean. Over the years the concept of "effectiveness" in particular, has been expanded by the FDA far beyond its plain meaning that a device should perform as its label says it does. Concepts such as the device must be demonstrated to have "usefulness" have become part of the FDA decision. This means that an FDA panel substitutes its judgment on usefulness for the judgment of a practicing physician who would like to use the product.

Particularly for products used only in the laboratory or by medical professionals, shouldn't we return to the plain meaning of effectiveness?

Response: Whatever can be done to more clearly specify the definitions of safe and effective would help eliminate the subjective nature of the FDA's use of the terms. Most people I know are particularly afraid of the creep of these definitions into ever-expanding mandates.

RESPONSES TO QUESTIONS FROM HON. JOHN D. DINGELL BY CHARLES E. JOHNSTON II, M.D.

Question: Dr. Johnston, your testimony mentioned that you licensed the idea for TSRH instrumentation to a start-up manufacturer, who then got FDA approval. Can you tell us how long FDA took to approve that application, and whether in your view FDA's review was competent?

Response: The time required to approve the application was a matter of a few months. This was because the application from the start-up manufacturer concerned devices which were modifications of devices already in existence prior to 1976. The approval was therefore "grandfathered" by the FDA due to the previous existence of these early devices. The FDA's review was competent.

Question: Do you have problems or criticisms of FDA's approval process as it relates to spinal fixation devices, based on your own experience?

Response: FDA's approval process for spinal fixation devices has, in general, confounded the efforts and best intentions of inventors and surgeons. This is because the FDA has crossed over into the realm of regulating the practice of surgery. As I explained in my interchange with Congressman Wyden, the FDA's role in approval of medical devices should primarily be one of documenting that the devices are safe and do not cause untoward effects simply by being present in the body. In the case of pedicle screws, the most commonly regulated spinal fixation device currently used, these devices have been in surgical practice for over 20 years, are known to be safe if they are appropriately placed, and the FDA limiting indications for these devices constitutes the FDA practicing and regulating spinal surgery, which is completely without precedent. Devices and techniques which do not produce better outcomes and results are quickly discarded by surgeons and physicians and it is the medical community's job to determine efficacy and usefulness of devices and procedures. There is a difference between a device which is safe to implant and produces a better outcome, a device which is safe to implant and does not produce a better outcome, and a device which is not safe to implant (regardless of outcome). FDA's role should only be to determine that a device is safe to implant. Outcomes are determined by the doctors that use them.

Question: I understand there was an orthopaedic and rehabilitative devices advisory panel... there was testimony from people injured by bent or broken screws. Don't patients that receive experimental therapies need some protection, like informed consent and oversight by Institutional Review Boards.

Response: Yes, patients that receive experimental therapies do need protection, which is usually provided and overseen by IRB's. The people who testified that they were "injured" by bent or broken screws have not been treated with an experimental procedure. They have had a spinal fusion—a tried and true accepted orthopaedic procedure which had been augmented by the use of internal fixation devices, under the belief that the internal fixation device would produce a more rapid and secure fusion, and give the patient a more rapid recovery with a better end result. The fact that the devices were bent or broken indicates that there were technical difficulties or errors in their implantation or the fusion simply failed to heal. Unfortunately, devices cannot put themselves into patients, and surgeons are only human, and good results are never guaranteed, and cannot be. The fact that these patients did not have a good result has no bearing on oversight by IRB's, as the therapy which failed is *not* experimental.

Question: You mention restrictions that FDA put on the use of the innovative artificial rib device. What was the source of the restrictions, and how were they communicated to you? Did you protest to FDA, and if so, what was its response? Was FDA requiring some sort of feasibility study to develop safety data, and if so, did it let the study go on to long?

Response: The artificial rib device was invented by a colleague in San Antonio, and the FDA restricted its use to only its inventor. No other surgeon or surgical center was allowed to use the device, even if that surgeon (myself, for example) had visited the inventor, performed surgery with the inventor to learn the technique, and was fully versed and qualified to perform the procedure. No specific protest was made to the FDA, because in our experience, such protests are ineffective, as the agency is usually unresponsive to such requests. A feasibility study was performed by the inventor. The inventor compulsively and carefully gathered safety and efficacy data for some 20 patients over a four-year period, in order to fulfill his FDA approval requirements. In terms of letting the study go on to long, I will only say that, in the opinion of the pediatric spinal specialists who would use such an innovative device, the inventor proved without qualification that the device was not only safe, but its results in these first 20 patients were nothing less than spectacular, since there was no other therapeutic modality available to offer to such patients. Continued restrictions of this device by the FDA withholds such treatment from numerous other patients who could benefit from it.

Question: You state in your testimony that you hope Congress "will act to confine the FDA to its proper role". What do you see as FDA's proper role? For example, is it needed to verify manufacturer's claim of safety and efficacy, thereby protecting device users as well as the ability of honest companies to compete?

Response: As I answered above, FDA is needed to verify the *safety* of implanted devices. Manufacturers will only market a device once the inventor, or a surgeon familiar with the inventor, has proven that the device can be safely implanted. Efficacy, however, can usually only be determined by careful analysis of patient outcomes and results. The medical community communicates amongst itself quickly on new procedures which work and are of benefit, and it discards procedures quickly which are of no benefit and do not work. FDA's approval of data determining efficacy is usually too little and too late, as the medical community has usually already made up its mind about efficacy by the time FDA's tedious process is complete. This is the situation, for example, in the opthamology field using the laser surgery to reshape and sculpt the lens, to make people not have to wear glasses. This is the situation with the prosthetic rib device, where the results already demonstrate superb efficacy, and the FDA's delay in approval is years behind the orthopaedic community's acceptance of this device.

RESPONSES TO QUESTIONS FROM HON. JOHN D. DINGELL BY NEIL KAHANOVITZ, M.D.

Question: Is it fair to say that your main concern is with FDA's delay in approving new uses for existing products, in conjunction with its efforts to limit unapproved uses?

Response: In all fairness, it would be more appropriate to state that my main concern as a practicing physician is to provide patients in this country with access to the most up-to-date drugs and devices available in a timely manner. The most important medical tenet that any physician should adhere to is "Physician do no harm." While providing the most up-to-date drugs and devices, the treating physician must rely on the work of the FDA to provide the safest drugs and devices humanly possible. As a physician who has treated victims of the Thalidomide tragedy, I see no substitute for the strictest scientific guidelines to evaluate new drugs and devices. However, the FDA must perform this duty within the time frames and guidelines legislated by the United States Congress.

Within my overall concerns, I am especially concerned with the FDA's delay in approving new uses for existing products through the 510(k) process. A device that is considered similar to a device previously approved for the American marketplace is found to be "substantially equivalent" through the 510(k) process. Thus it is not truly an approval process, but merely a determination of equivalency with a device currently available in the American marketplace.

The recommended time frame for this equivalency determination is 90 days. Unfortunately, it has been a number of years since this time frame has been kept. Dr. Kessler recently testified to Congress that the median review time for a 510(k) device was 98.5 days by January 1995. This is merely an example of statistical manipulation. The average or mean time for 510(k) review in FY94 was actually 184 days, almost twice as long as the median figure of 98.5 days quoted by Dr. Kessler. This simply reflects the fact that a number of devices are taking significantly longer to be reviewed than the use of median statistics would indicate.

Another difficulty encountered in trying to assess the exact time of submission to release of a new device is the method of "timekeeping." The FDA timekeeping clock does not start until the review process is begun by the FDA, not when the application is submitted. Further timekeeping ambiguities may arise when the FDA asks for additional data or clarification and an official "time out" occurs. The clock may also be stopped or even restarted if a manufacturer is asked to significantly amend or resubmit its application.

Thus we must not be deceived by statistical trickery or timekeeping aberrations. The American public asks for no more and certainly no less than that the FDA review devices through the 510(k) process within the legislated time frames. What is absolutely imperative is honesty on the part of the FDA in the practice of reporting the times it takes to determine equivalency, from application filing to equivalency determination.

In conjunction with the current dilemma in the review process, I am equally concerned about the efforts of the FDA to monitor or police the practice of medicine. The FDA has been given the formidable task of protecting the American public from unsafe drugs and devices. Nowhere, to my knowledge, has the FDA been legislated the job of monitoring the way physicians practice medicine beyond providing them with safe drugs and devices to be used while carrying out the practice of medicine. If the FDA were to strictly adhere to its legislated tasks, the intrusion of the FDA into the clinical practice of medicine results from the confusion over the off-label use of drugs and devices would end. The ongoing unresolved controversy of off-label use will be discussed further in the subsequent questions; however, legislative clarification of the off-label use controversy as well as adherence by the FDA to the legislated Congressional time frames would be a giant step forward in remedying my concerns.

Question: Isn't it important that data be collected and submitted by the sponsor before a particular use is approved for the label?

Response: There is no question that the appropriate data must be collected and submitted by the sponsor to ensure that the process of device or drug evaluation proceeds in a timely manner. Although this panel hearing focuses on potential problems existing within the FDA process, there can be no substitute for submission of the appropriate data by the sponsoring manufacturer to allow the FDA to perform its primary role of evaluating and determining the safety of a drug or device. Without the appropriate and timely submission of data, the FDA obviously cannot perform this function within the legislatead time frames.

However, there must be an attempt on the part of the FDA to clarify exactly what data is needed from the sponsors prior to the institution of the approval process. Establishing the needs of the agency prior to the beginning of the review process would surely enhance the speed with which devices and drugs are reviewed and thereby avoid lengthy delays caused by amendments to a previously submitted application as a result of calls for new or additional data on the part of the FDA, or worse, complete resubmission of an application found to be delinquent by the FDA part way through the process. Thus, communication between the sponsor and the FDA reviewers is critical prior to submission of the application. In this way, delays and interruptions in the review process may be minimized by ensuring that all data needed by the FDA to proceed with the review process is clearly communicated to the sponsor.

Many of the outcries by the manufacturers of unnecessary delays on the part of the FDA as well as complaints of insufficient sponsor data by the FDA may be avoided by bringing the two parties together prior to the official start of the review process. This seemingly commonsense approach of bringing both the manufacturer and the FDA to the table prior to the review process would certainly make the job of collecting data easier as well as streamlining the job of the FDA by eliminating unnecessary delays due to inadequate data submission. Whether it necessitates Congressional legislation or simply a more thoughtful, courteous approach by both the sponsoring manufacturer and the FDA, the current adversarial stance of these parties must be allayed, since the real victim of this struggle is neither the manufacturer nor the FDA, but the American patient.

Question: Is it true that sponsors of already marketed products are often reluctant to spend money on additional clinical trials for other uses when doctors can already use the device for that purpose? If so, doesn't this impede efforts to collect data systematically so that risks and benefits can be properly assessed?

Response: Reluctance on the part of the sponsor to spend money on additional clinical trials for secondary uses of a device when that device is already approved for another use will continue until the confusion over off-label use is clarified. Unquestionably, this current situation clearly impedes the ability of the FDA to ascertain the risks and benefits of a device used in this manner. Within the medical community, there is no clear understanding on the part of the physicians, manufacturers and ultimately the patient as to what constitutes an off-label use or when a secondary use of a device must go through the 510(k) or even the PMA process.

There is no clear differentiation between off-label use, unapproved or illegal use of a device. Following the release of a device for a specific clinical indication, what defines for that particular device the clinical boundaries within which that device is approved or considered on-label? Conversely, at what clinical juncture does the use of that device become off-label and at what point in the clinical process is new data to be collected and submitted for further clinical expanse of the use of that device's on-label use?

For example, a new total joint replacement deemed safe, efficacious and on-label may be approved for the treatment of osteoarthritis, the most commonly encountered degenerative disease affecting joints. However, there is a wide range of degenerative or arthritic diseases affecting human joints that lead to the same type of debilitation as does osteoarthritis, but clearly does not fall within the clinical realm of osteoarthritis. Does the sponsor begin clinical trials for such non-osteoarthritic diseases such as rheumatoid arthritis, congenital hip disease or a wide variety of inflammatory arthritic conditions that would benefit from total joint replacement? For those more unusual or rare diseases needing total joint replacement, can the sponsor justify lengthy expensive clinical trials for those few patients that would benefit from these devices, or should the sponsor disregard these unfortunate individuals because the collection of data for a device used within this small group of patients is clearly not cost-effective? The FDA must resolve this confusion over off-label use.

The very basis for this confusion may be the distinction of exactly when the FDA's policing of safety end and the regulation of clinical practice begin. Many of the more common instances of off-label use would no longer be considered controversial if the FDA would only assess the safety and efficacy of a device and then allow physicians to determine the best clinical use of those products.

Question: You term the FDA's process a "bureaucratic mire." This Subcommittee in the past has done a comprehensive look at the process, and laid out its concerns in its 1993 report. Can you outline the specific problems you see, and what you think has caused them?

Response: The problems that exist today are essentially the same problems that existed at the time of the 1993 report. Delays in the review and approval process continue to rise despite claims of increased and improved efficiency. The FDA openly defies the time frames and mandates governing the review and approval process legislated by the United States Congress. Simple compliance with these mandated guidelines would go a long way in improving the "bureaucratic mire."

As discussed above, clarification and a clear definition on the part of the FDA as to what exactly designates off-label use would also help in the resolution of the "bureaucratic mire." Fear of medicolegal repercussions arising from the mistaken equation of off-label use with unapproved or illegal use would end. Thus patients being denied care solely on the basis of fear of medicolegal reprisal would end, resulting in an improved quality of life for countless patients.

The third area needing reform is the ever-increasing tendency of the FDA to attempt to regulate and police the clinical practice of medicine when in fact their sole responsibility is the protection of the American public from unsafe drugs and devices. This specific problem will be further discussed in the response to the next question. Any attempt to ensure that the FDA returns to working within the Congressionally mandated guidelines, defining off-label use and stopping the FDA's growing tendency to practice medicine will certainly result in these parts of the overall problem equalling the true sum that the American taxpayer deserves.

Question: Obviously, off-label uses would appear to have significant benefits for the public, but they could also cause significant harm. How would you address the possible harm, assuming for the moment that FDA cannot get more resources and that delays in approving new uses will continue?

Response: No example more clearly illustrates off-label use than aspirin. Nowhere is there any reference to the use of aspirin being approved on the product label for use in the prevention of blood clots. However, this off-label use of aspirin is exceedingly widespread despite the small number of patients who have allergic reactions, gastrointestinal upset and, more rarely, fatal gastrointestinal bleeding due to the risks of taking aspirin. As stated a number of times, the FDA must keep unsafe drugs and devices off the market. No one would ever want another Thalidomide tragedy, but anyone involved in the medical profession realizes, as must the American public as well as Congress, that medicine is still an art as well as a science. The human body is not a machine, and until we as scientists and physicians understand significantly more about how this complex organism works, there will always be complications, big and small, associated with the use of any drug or device. without accepting this fact, medical advancements would cease to exist. Would we have ever allowed Penicillin to be sold given its small but recognizable incidence of deadly allergic reactions?

Given the fact that the FDA provides safe drugs and devices for the American public, there will always be instances of improper use of that drug or device caused by poor clinical judgment on the part of the treating physician. A clear example of this dilemma was illustrated by the investigative report on 20/20 (ABC) of the use of pedicle screws. On that telecast, the vast majority of examples of poor outcome presented were victims of poor clinical judgment as a result of the poor patient selection who had this surgical device implanted. Thus, there must be no confusion over an expose of the poor practice of medicine with its attendant poor clinical results and the expose of a device that when used properly has been documented to be not only safe but also efficacious. Patients should not be denied access to devices based upon the actions of a very small minority of physicians when the overwhelming majority of physicians practice within the realm of good clinical medicine.

The question as to who should be policing the practice of medicine is a difficult one to answer. There is no clear consensus as to whether this duty falls on the shoulders of the state medical boards, medical specialty societies, hospital credentialing boards or even the malpractice attorneys, but one thing should be absolutely clear. The enforcement agency should not be the FDA.

Question: Do you really think that the FDA is acting in bad faith on off-label uses, seeking "only to protect its self-perpetuating bureaucracy?"

Response: Given the fact that the budget for the FDA continues to rise and the number of employees continues to increase while the number of drugs and devices brought to the American patient fails to parallel this growing outlay of tax dollars; given the fact that the FDA continues to defy the time frames set forth by the United States Congress; the FDA is unable to clarify such problems as off-label use while continuing to attempt to police and regulate the clinical practice of medicine, then yes, I would have to honestly say that the FDA is acting in "bad faith"

Responses to Questions from Hon. John D. Dingell by Dr. Edward Yavitz

Question: You advocate that after the first approval of a new device, all subsequent devices should be automatically down-classified. Such an action would allow new companies to get a competitor product to market without the kind of data and information that the first company was required to produce, and to have that device on the market very soon after the approval of the innovator product. Wouldn't that reduce incentives for innovation and, over the long term, mean it will be less likely that patients will have the benefit of truly creative ideas and technology? In such a system, why wouldn't most companies simply wait for their competitors to do all the premarket testing and incur associated costs, and then just come in with a "me-too" product?

Response: I disagree with two of the premises in this question. First, the assumption that if Congress required down-classifying all devices from Class Ill to Class 11 as soon as the first manufacturer has proven safety and efficacy through a multi-year PMA application, that competitor companies would get a free ride. I must re-mind you that Class 11 requires the FDA to place special controls regarding production, user training, patient education, performance standards as measured by postmarket surveillance and patient registries. The secondary companies would have to prove equivalency through a 510K application which currently takes a year to process. Therefore, the first company to apply and receive PMA approval will have several distinct advantages over its rivals. It will be first to market with at least a year head start. It will generally have the first patent protection. It will be the first to the venture capital trough. But if a competitor can really improve upon the cost or effectiveness of the device why should an unnecessary regulatory delay force doctors to waste precious medical dollars on the first generation device?

The second incorrect assumption is that shortening the time to market for competitive and innovative improvements to the pioneer device will reduce incentives for innovation. It is exactly the opposite. Why do we see so many new medical devices and upgrades of existing devices unveiled in Europe instead of the USA? Because secondary manufacturers cannot afford the full PMA process here. Improvements to medical devices are being made faster than the FDA can process them because the FDA is persevering , putting each manufacturer through a redundant 3 year process of testing as if their device was totally new when it is only an improvement on an already approved device.

Congress should instruct the FDA to be "profit blind" in its charge to protect the public from unsafe or useless devices. If a company can show it has an equivalent device to one that has passed stringent PMA procedures and passes the special controls established for such a device by the FDA it should be allowed to go to market. More competition means better devices and lower prices for the public. The profitability is no concern of the FDA.

In the business arena outside of FDA control there are numerous examples such as computer software development, where there are huge premarket testing and development costs and where "me-too" clones exist, yet there is incredible innovation and value created for both manufacturers and users alike. The FDA is a totalitarian element in an otherwise free-market society.

Question: Dr. Yavitz, you obviously want the best and most advanced instrumentation for your patients. But would you want to use such instrumentation with patients if there were not good evidence of safety and effectiveness? Would you be willing to rely on testimonials or assertions by a manufacturer or a salesman that a product is safe and effective? What percentage of your patients who need delicate eye surgery would agree to the use of an instrument or device which you told them had not been tested, reviewed, and approved for safety and effectiveness?

Response: If a manufacturer proved to the FDA that it was constructing an instrument which worked along the same principals as a previous device which had been tested for 3-4 years and passed the PMA process I would have full confidence in using the instrument. By my own experience and that of my colleagues published weekly in trade papers, I would know very quickly whether such a device was safe and effective in the field. Remember the testimony of my panel colleague Dr. Nobel, who said that most injuries occur with approved devices. FDA Class Ill approval does not guarantee safety or effectiveness.

You ask what percentage of my patients would submit to the use of an unapproved device? I was an investigator for the first folding silicone implants which replace cataracts. None of these devices were approved. They were all under study. Yet 200 patients out of 200 that I asked agreed to have them placed inside of their eyes for the rest of their lives when I told them that I personally felt they would work. I was relying on the testimonials of the manufacturer and the experience of my colleagues. In my medical judgement, folding silicone implants had advantages over existing approved solid plastic implants.

Question: Dr. Yavitz, you seem to advocate greater participation of clinicians in the evaluation and decision about marketing new medical devices. Wouldn't waiting for consensus among physicians tend to delay a final decision even more? And, while physicians are deciding on their own opinions of products, wouldn't at least some patients be exposed to relatively ineffective and potentially unsafe treatments with unproven products?

Response: Now for the third question. I advocate a larger role for clinicians in the marketing of new medical devices because it is our reputations and the well being of our patients that are at stake. Doctors after all will be the final decision makers whether you like it or not. We will use devices that work and shun those that are too expensive or that fail to work even if they are FDA approved. When Congress allows the FDA to retest similar devices for many years instead of allowing those with modifications that improve health care to go to market in a timely fashion, you are exposing patients to relatively ineffective and potentially unsafe treatments with obsolete products.

Let me give you another example. I mentioned excimer laser as a device which has languished in the FDA PMA process for so long that when they approve this laser for sale in the United States for the purpose of sculpting and reshaping the cornea of the eye to reduce dependency on glasses, the machine will be obsolete and perhaps dangerous compared to current generations of the device available abroad. This device has been used in almost every country outside the USA, including the Bahamas for the past 6 years. The delay in FDA approval has been warranted because of inadequate results from the first generation of this laser and in the way in which it was first used. But rather than allowing the equipment and techniques to evolve naturally as they have in other countries, the FDA refuses to allow companies to change or improve their protocols or devices once a study has begun. So we will be forced to use an obsolete machine in a manner that no one uses anywhere but in the US, specifically, the Summit Omnimed Excimer Laser using a 5mm size treatment zone. The machine and the size of the treatment zone have been long abandoned elsewhere due to complications of glare and haze, which are eliminated by using lasers with smaller beams that scan the surface with lower power and use larger 6 or 7 mm treatment zones. But it will take the FDA 2-3 more years to approve the improved lasers and treatment zones. By that time, other improvements will be made and will be out of reach for American citizens.

The improved lasers available in the Bahamas or anywhere but the USA are 115 the size of the Summit laser, use 1150 the toxic gas, achieve a smoother ablation for faster healing with less haze and automatically track small eye movements to prevent decentered treatments which occur in 12% of patients with the Summit laser. They also cost half as much to purchase and 1/10 as much to maintain. And even though Summit will receive royalties from any future excimer laser maker on its basic patents, it wants to be the only FDA approved machine for 3-4 years despite the existence of superior machines all over the world. The public loses, the doctors lose, the FDA loses when poor results pour in compared to newer generation machines and only Summit wins. That makes no sense. The FDA approval process was not meant to protect manufacturers from competition. It was established to protect the public. Your job as an oversight committee is to be sure that it does so in the most expedient and efficient manner possible.

Question: When a physician is using an untested, or unproven, device, doesn't that potentially deprive patients of other treatments that are known to be effective, and delay effective treatment while these patients are being used as guinea pigs, whether they know it or not?

Response: This leads to the answer to your last question, if I may skip the third question for a moment. In this example I was using an unproven, that is, unapproved device and I was depriving my patients of an alternative treatment that was known to be effective. But in doing so I proved that silicone implants in the eye were superior to known and approved hard plastic implants in terms of faster healing and less scarring of the eye. This is how medicine advances. By unduly delaying and limiting physician's choice of instruments and drugs, the FDA is dictating the practice of medicine. If modern medical devices were approved more quickly it would lead to greater patient satisfaction and improved care. Ron Wyden asked the physician panel to comment on his fear that patients will be at greater risk if the PMA process were streamlined and tort reform gave limited immunity to doctors and manufacturers. I would like to answer by reminding him that the medical community is monitored by institutional review boards, quality assurance committees and peer review boards all of which independently and randomly select charts and assess the safety and appropriateness of medical care. There are plenty of safeguards for the patient. FDA footdragging does not protect patients. Congress should strike the Rule of 4 and require the FDA to automatically reclassify any PMA approved medical device from CLASS III to Class II. Then the FDA could not hide behind the Rule of 4 which allows them to perseverate, putting each manufacturer through a redundant 3 year process of testing as if their device was totally new when in fact it is just an improvement on an already approved device.

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